

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

**PLAINTIFFS' RESPONSE TO
DEFENDANTS C. R. BARD, INC.'S AND
BARD PERIPHERAL VASCULAR,
INC.'S MOTION TO EXCLUDE THE
OPINIONS OF ROBERT O. RITCHIE,
PH.D.**

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EXHIBIT A

“Recovery™” Vena Cava Filter: Experience in 96 Patients

Sanjeeva P. Kalva, Christos A. Athanasoulis, Chieh-Min Fan, Marcio Curvelo, Stuart C. Geller, Alan J. Greenfield, Arthur C. Waltman, Stephan Wicky

Department of Radiology, Massachusetts General Hospital, Boston, MA, USA

Abstract

The purpose of the study was to assess the clinical safety and efficacy of the “Recovery™” (Bard) inferior vena cava (IVC) filter. We retrospectively evaluated the clinical and imaging data of patients who had a “Recovery™” IVC filter placed between January 2003 and December 2004 in our institution. The clinical presentation, indications, and procedure-related complications during placement and retrieval were evaluated. Follow-up computed tomography (CT) examinations of the abdomen and chest were evaluated for filter-related complications and pulmonary embolism (PE), respectively. “Recovery” filters were placed in 96 patients (72 males and 24 females; age range: 16–87 years; mean: 46 years). Twenty-four patients presented with PE, 13 with deep vein thrombosis (DVT) and 2 with both PE and DVT. The remaining 57 patients had no symptoms of thromboembolism. Indications for filter placement included contraindication to anticoagulation ($n = 27$), complication of anticoagulation ($n = 3$), failure of anticoagulation ($n = 5$), and prophylaxis ($n = 61$). The device was successfully deployed in the infrarenal ($n = 95$) or suprarenal ($n = 1$) IVC through a femoral vein approach. Retrieval was attempted in 11 patients after a mean period of 117 days (range: 24–426). The filter was successfully removed in nine patients (82%). Failure of retrieval was due to technical difficulty ($n = 1$) and the presence of thrombus in the filter ($n = 1$). One of the nine patients who had the filter removed developed IVC thrombus after retrieval and another had an intimal tear of the IVC. Follow-up abdominal CT ($n = 40$) at a mean of 80 days (range: 1–513) showed penetration of the IVC by the filter arms in 11, of which 3 had fracture of filter components. In one patient, a broken arm migrated into the pancreas. Asymmetric deployment of the filter legs

was seen in 12 patients and thrombus within the filter in 2 patients. No filter migration or caval occlusion was encountered. Follow-up chest CT ($n = 27$) at a mean of 63 days (range: 1–386) showed PE in one patient (3%). During clinical follow-up, 12 of 96 patients developed symptoms of PE and only 1 of the 12 had PE on CT. There was no fatal pulmonary embolism in our group of patients following “Recovery” filter placement. However, the current version of the filter is associated with structure weakness, a high incidence of IVC wall penetration, and asymmetric deployment of the filter legs.

Key words: Thrombo-embolism—IVC filters—Retreivable filters—Pulmonary embolism—Deep venous thrombosis

Venous thromboembolic disease is associated with significant morbidity and mortality [1]. Anticoagulation is the accepted standard therapy for venous thromboembolism. However, in a small number of patients, anticoagulation might be ineffective or associated with increased risk of hemorrhage [2]. In addition, anticoagulation might be contraindicated due to the presence of heparin-induced thrombocytopenia, central nervous system malignancy, and cranio-spinal trauma and during the perioperative period of major surgery. In these circumstances, caval interruption by various methods has been accepted as an alternative to anticoagulation to prevent pulmonary embolism (PE) [3, 4]. During the past decade and with the availability of percutaneously implantable inferior vena cava (IVC) filters, there has been a major increase in the number of filter implantations [5]. Additionally, prophylactic placement in the absence of documented venous thromboembolic disease has been on the rise in patients with orthopedic and spinal trauma [6] or during surgery [7]. The incidence of complications related to permanent vena cava filters is small [8, 9]. However, there are concerns about their long-term safety [10], especially in young patients, with high life expectancy. Temporary filters have been recommended for

Correspondence to: Sanjeeva P. Kalva, GRB 290 MGH, 55 Fruit Street, Boston, MA 02114, USA; email: skalva@partners.org

patients who require short-term protection against PE [11], but they are not favored due to concerns about filter thrombosis, infection, and dislocation of the device. Recently, retrievable filters have been introduced with the options of using the device as a temporary filter or as a permanent one if clinically indicated [12]. Several devices are available. Early data on retrievable filters are encouraging, but the number of patients is small [13–15]. Long-term data are lacking. The purpose of our study was to evaluate the clinical safety and efficacy of one of these retrievable devices, the "RecoveryTM" IVC filter (CR Bard, Murray Hill, NJ).

Materials and Methods

This study was approved by our institute's Human Research Committee. This study also complies with the Health Insurance Portability and Accountability Act.

From the Interventional Radiology database (Hi-IQ system), we identified patients who had a "Recovery" filter placed from January 2003 through December 2004. The clinical data of these patients were retrieved from the hospital's electronic medical records and imaging data were retrieved from our Picture Archiving and Communication System (PACS, Agfa Impax, version 4.5; Agfa, Belgium). All data were entered into a database (Filemaker pro 7; Filemaker Inc, Santa Clara, CA, USA).

Demographic data, clinical presentation at the time of filter placement, underlying medical conditions, and indications for filter placement were recorded. The reports of imaging studies pertaining to venous thromboembolism such as the presence of PE, the location of the PE, and the presence and location of deep venous thrombosis (DVT) were reviewed. Imaging studies for the detection of PE included computed tomography (CT) pulmonary angiography (CTPA), and conventional catheter pulmonary angiography (CPA). The imaging studies for the detection of DVT included CT indirect venography of the thighs and pelvis (CTV), and compression ultrasound (CUS) of the thighs for the evaluation of femoro-popliteal veins.

Design of the "Recovery" Filter

The "Recovery" filter consists of 12 shape-memory nitinol wires (0.013 in.) emanating from a central nitinol sleeve (or hub). These 12 wires form 2 levels of filtration of emboli: The filter legs provide a lower level of filtration and the arms provide the upper level. The legs have hooks that attach to the caval wall. The arms do not have hooks. The resting diameter of each of the arms is 30.5 mm, and 32 mm for each of the legs. The filter measures 40 mm in height. The "Recovery" filter is intended to be deployed in the IVC with a diameter less than or equal to 28 mm. The filter is deployed through a 7F (inner diameter) sheath. The filter can be introduced by either femoral or jugular vein approach. However, it can be retrieved only through a jugular approach. The retrieval device consists of a retrieval cone constructed from nine metal claws, covered with a urethane membrane. The cone is placed over the hub of the filter, and the outer sheath (10F) is advanced to collapse the cone in such a way that it captures the hub. The entire filter is then pulled into the outer sheath and removed. The hooks of the filter legs are designed so that the device can be pulled into the sheath.

Filter Deployment and Retrieval

In all patients, the filter was deployed according to a standard departmental protocol. Informed consent was obtained. The common femoral vein was accessed in an antegrade fashion and a 5F pigtail catheter was placed at the common iliac vein confluence. Cavagraphy was performed using 30 cc of contrast material injected at a rate of 20 cc/sec (Ultravist 300 or Magnevist or CO₂). The renal veins were identified. The pigtail catheter was exchanged for the filter delivery system and the filter was deployed at the desired location. A contrast cavagram was again performed to check the position of the filter and to detect any potential problems. The filter delivery system was removed and hemostasis was achieved with manual compression. All patients were advised to keep the accessed leg flat for 4 h following the procedure. Procedure-related information was recorded, including approach for filter delivery, vena cavagram findings (presence of thrombus, congenital caval anomalies, anatomic variations, extrinsic compression), location of the filter, and complications during and following filter placement.

Filter retrieval was carried out through a jugular venous approach and a standard protocol was followed. The right internal jugular vein was accessed under ultrasound guidance, using a micro-access system. A 5F pigtail catheter was placed in the IVC below the filter. A contrast cavagram was obtained. The pigtail catheter was removed and the filter retrieval system was introduced over a wire. The tip of the filter was engaged through the recovery cone and the filter was pulled into the outer sheath and removed. A contrast cavagram was again obtained. The jugular vein sheath was removed and hemostasis was achieved with manual compression. Details of the retrieval procedure, including time duration from placement to retrieval, vena cavagram findings, technical difficulties, results, and complications of the procedure, were recorded.

Clinical and Imaging Follow-up

In all patients, clinical occurrence of PE or DVT on follow-up was recorded. In patients who had clinical evidence of PE, the pertinent imaging data (CTPA and ventilation perfusion scintigraphy) were reviewed for the presence and location of pulmonary emboli. Similarly, the imaging studies for DVT were reviewed and the findings were recorded. In patients who had a contrast-enhanced abdominal CT for any clinical reason after filter placement, the CT images were reviewed for location of the filter, penetration of the IVC wall by the filter legs (>2 mm beyond the caval wall), fracture of the device components, migration of fractured components, asymmetric deployment of the filter legs (where the filter legs after deployment are not equidistant and are clumped), presence of filter tilt (>25° tilt with the long axis of the IVC), and presence of thrombus in the cava or in the filter. Similarly, whenever a contrast-enhanced chest CT was available after filter placement, the CT images were reviewed for the presence of main and lobar PEs. A contrast-enhanced chest CT was performed on a multidetector CT (4-slice or 16-slice CT) at a maximum slice thickness of 5 mm during the arterial phase for the evaluation of pulmonary parenchyma.

Study End Points

The efficacy of the filter was assessed by the occurrence of PEs during clinical and imaging follow-up. The safety of the filter was assessed based on the technical difficulties during deployment and

retrieval and the occurrence of symptomatic or asymptomatic filter-related complications during follow-up.

Results

There were 72 males and 24 females (Table 1). The mean age at the time of filter placement was 46 years (range: 16–87; median: 46 years). Thirty-nine patients had signs and symptoms of venous thromboembolism when filter placement was requested. Thirteen patients had symptomatic DVT; 24 patients had symptoms of PE and 2 had clinical evidence of DVT and PE. The underlying clinical condition was trauma in 58 of 96 (60%) patients, postoperative state in 11 (12%), malignancy in 6 (6%), stroke in 5 (5%), preoperative state in 2 (2%), and other miscellaneous conditions in 14 (15%). None of the patients had clinical evidence of upper-extremity DVT.

Twenty-six patients had CTPA performed as a part of the workup for the PE and one patient had both CTPA and CPA. Of these 27 patients, 6 had main pulmonary artery embolism, 6 had lobar, 11 had segmental PE, and 4 had no evidence of PE.

Thirty-three patients had CUS and 23 had indirect CTV for the evaluation of DVT. Eight patients had right femoro-popliteal venous thrombosis, eight had left femoro-popliteal venous thrombosis, and four had bilateral femoro-popliteal venous thrombosis. Two patients had left iliac vein thrombosis and one had right iliac vein thrombosis. There was no deep venous thrombosis in 34 patients.

The indications for filter placement were as follows (Table 1): contraindication to anticoagulation in 27 of 96 (28%) patients, complications of anticoagulation in 3 (3%), failed anticoagulation in 5 (5%), and prophylaxis against pulmonary embolism in 61 (64%). A prophylactic filter was placed in patients with level-3 trauma [head injury with intracranial bleed ($n = 37$), trauma to spine ($n = 8$), pelvic/hip fractures ($n = 8$), abdominal trauma with major organ laceration ($n = 2$)], during perioperative state when risk of pulmonary embolism was considered very high ($n = 5$), and in one patient with hemorrhagic stroke.

Filter Deployment

A right femoral venous access was used in 82 of 96 (85%) patients, and a left femoral vein was used in 14 (15%). A vena cavagram showed patent IVC in 95 patients and 1 patient had infrarenal caval thrombus. One patient had left-sided IVC and another had compression of the left common iliac vein by the right common iliac artery with no thrombus. The diameter of the IVC ranged from 19 to 28 mm. The filter was deployed in an infrarenal location in 95 of 96 (99%) patients. In one patient, the distance between the more inferior renal vein and the iliac vein confluence was less than 3 cm and the suprarenal location was chosen for filter placement. The filter was successfully deployed in all patients with no technical difficulties. A vena cavagram

Table 1. Results

Demographics	
Total No. of patients	96
Male	72 (75%)
Female	24 (25%)
Mean age	49 years
Indications for filter placement	
Contraindication for anticoagulants	27 (28%)
Complications following anticoagulant therapy	3 (3%)
Failure of anticoagulation	5 (5%)
Prophylaxis against PE	61 (64%)
Clinical follow-up	
Mean follow-up period	160 days
Clinical signs of PE following filter placement	12 (12.5%)
Imaging evidence of PE	1 (1%)
Imaging follow-up	
No. of patients having abdominal CT	40 (42%)
Mean follow-up period	80 days
Caval thrombosis	0 (0%)
Penetration of cava	11 (27.5%)
Clumping of filter legs	12 (30%)

obtained after the placement of the filter showed no caval injury or significant tilt (>25%) of the filter. Asymmetric deployment of filter legs was not observed on the vena cavagram. There were no procedure-related complications.

Filter Retrieval

Filter retrieval was carried out when the patients were considered not to be at risk for developing a venous thromboembolism. Filter retrieval was attempted in 11 of 96 (11.5%) patients after an average period of 117 days (range: 24–426 days; median: 70 days) following filter placement. In one patient, there was thrombus in the filter on the initial vena cavagram, and the filter was not retrieved. In another patient, the filter could not be retrieved due to technical difficulty. The filter was tilted and the hub of the filter could not be successfully engaged into the retrieval cone. Multiple attempts to reorient the filter were not successful. The filter was successfully retrieved in 9 of 11 (83%) patients. In one of the nine patients, there was technical difficulty during the retrieval process due to a tilt of the filter. The filter was repositioned using a pigtail catheter and a tip-deflecting wire and then the filter was successfully retrieved. A vena cavagram after filter retrieval showed thrombus attached to the caval wall at the level of the filter hooks in one patient and an intimal tear at the level of the filter hooks in another.

The filter was not retrieved in 85 patients. Four patients with malignancy and four patients with stroke were considered at risk of continuous thromboembolic disease and the filter was not removed. In the remaining patients, the exact reason for not retrieving the filter was not stated in the patient records.

Follow-up

A clinical follow-up after filter placement was available in all patients (Table 1) for a mean period of 160 days (range:

1–554 days). Eighty-four patients had at least 12 days of clinical follow-up following filter placement. Twelve of the 84 (14%) patients had signs and symptoms of PE after an average period of 67 days (range: 3–220 days) following filter placement. In 4 of the 12 patients, the symptoms of PE occurred within 14 days following the filter placement. Four of these 12 patients had CT-documented PE prior to filter placement. Ten of 12 patients had CT pulmonary angiography. Of these, one patient had recurrent segmental PE and nine had no evidence of PE. Two of 12 patients had ventilation–perfusion scintigraphy that showed a low probability of PE. Three patients were on therapeutic doses of an anticoagulant following filter placement and none of these developed PE. There was no documented PE following prophylactic filter placement in patients with level-3 trauma. Following retrieval, six patients were clinically followed for a mean period of 160 days (range: 36–443 days) and none had recurrent PE. There were no adverse clinical consequences in the patient who had the intimal tear following filter removal.

A contrast-enhanced abdominal CT was available in 40 of 96 (41.6%) patients (Table 1) after a mean period of 80 days (range: 1–513 days) following filter placement. One patient had thrombus within the filter and another had thrombus in the vena cava below the filter. There were no total cava occlusions. In all patients, the filter legs abutted the caval wall. However, the filter legs were asymmetrically deployed (Fig 1) or there was clumping of the filter legs in 12 of 40 (30%) patients. The filter arms penetrated the IVC wall in 11 (27.5%) patients. In 3 of these 11 patients, the arms were fractured (or acutely bent). In one patient, the fractured arm migrated to the pancreas (Fig 2). In the other two patients, the fractured arms were attached to the main device protruding into aorto-caval space. In 5 of these 11 patients, the filter arms were seen protruding into other organs such as the duodenum ($n = 4$) and liver ($n = 1$). In the remaining three patients, the filter legs were seen 2 mm outside the caval wall without obvious penetration of any organ. All of these patients were asymptomatic.

A contrast-enhanced chest CT was available in 27 of 96 (28%) patients after a mean period of 63 days (range: 1–386 days) following filter placement. Ten patients had CTPA due to clinical suspicion of PE. One of the 10 patients had segmental PE. Seventeen patients had a chest CT as a part of other disease conditions unrelated to PE. None of the 17 patients had main or lobar pulmonary artery emboli.

An imaging study was performed for the evaluation of DVT in 53 of 96 (55%) patients after a mean period of 41 days (range: 1–227 days) following filter placement. Forty-five patients had CUS and 8 had CTV. Ten (10 of 53 or 18%) patients had DVT at a new site where no vein thrombosis was present prior to filter placement. Of these 10 patients, 8 had femoro-popliteal venous thrombosis and 2 had iliac vein thrombosis. Four patients had thrombosis at the venous access site.



Fig. 1. A 28-year-old male patient following a motor vehicle accident and cranio-spinal trauma received a prophylactic "Recovery" filter. Abdominal CT performed 45 days following filter placement shows asymmetric deployment of the filter legs in the IVC (arrow).

Discussion

Concerns about the long-term safety of IVC filters have stimulated interest in the development of a device that could serve as a permanent filter with an option of retrievability [16, 17]. Such optional filters are configured in a way similar to conventional filters but with certain modifications relevant to cava wall attachment [12] and with the addition of a hooklike structure at either end of the filter for retrievability [18]. These filters can be retrieved within a device-specific predetermined time frame. Currently in the United States there are three Food and Drug Administration-approved "optional" retrievable filters: the "Gunther tulip" filter (Cook Inc., Bloomington, NJ; approved as retrievable filter in 2003), the "Recovery" filter (CR Bard; approved as retrievable filter in 2003), and the "Optease" filter (Cordis Endovascular, Warren, NJ; approved as retrievable filter in 2004). These three devices had secured initial approval as permanent filters (Gunther tulip in 2000; "Recovery" in 2002, and Optease in 2002).

Anticoagulation has been accepted as an effective treatment for venous thrombosis and PE. IVC filters have been used for the prevention of PE in patients with contraindications to anticoagulation, in others who develop compli-



Fig. 2. A 20-year-old male patient received a prophylactic “Recovery” vena cava filter following trauma. Forty-two days following filter placement, abdominal CT showed penetration of the vena cava by the filter arms with migration of fractured filter arm components into the pancreas (arrow).

cations following anticoagulation, and in patients who develop recurrent PE despite adequate anticoagulation. Recently, there has been increasing use of IVC filters in the presence of free-floating ilio-femoral vein thrombus and in patients with high risk for the development of thromboembolic disease (after trauma, major surgery, or during thrombolysis procedures) [19]. In a randomized trial, Decousus et al demonstrated that IVC filters were effective in preventing PE, but the benefits were counterbalanced by an increased risk of DVT [20]. This has led to an increased interest in the development of optional filters, as these devices can be retrieved when the patient no longer needs protection. Also, they offer the option of leaving the device permanently if required.

Animal experiments in sheep have shown 100% successful retrieval of the “Recovery” filter in place for 12 weeks, with minimal trauma to the IVC [21]. Asch has reported an initial experience in humans with 100% successful retrieval at a mean implantation period of 53 days (maximum: 134 days) [13]. In addition, the filter was found to be effective in preventing PE. The author also described technical difficulties encountered during retrieval due to the tilt of the filter [13]. Other reports showed that retrieval might be feasible after an extended period of implantation [18]. In our study, we found that the filter was effective in preventing PE. Twelve of 96 patients developed clinical signs of PE following filter placement, but only 1 of the 12 had PE on imaging studies. We also observed that the filter could be retrieved even after prolonged periods of implantation. In our study, the longest implantation period before retrieval was 426 days. During retrieval in two patients, we encountered technical difficulties similar to those described by Asch [13]. Asymmetric deployment of the “Recovery” filter legs has not been previously reported. This might be

due to the lack of follow-up imaging studies after filter placement. In our study, asymmetric deployment of the filter legs was noted in 12 of 40 patients who had abdominal CTs. Although controversy exists about the significance of the asymmetric deployment of the filter legs [22, 23], there was no increase in the incidence of PE or caval thrombosis in those patients. Penetration of the IVC wall by the filters has been reported and the incidence varies from 9% to 24% [8, 9]. We found a high incidence of IVC wall penetration by the filter arms. Eleven of 40 patients showed penetration of the IVC wall by the filter arms. In two patients, the filter arms were in the aorto-caval space lying close to the aortic wall. Although these patients were asymptomatic, a few cases of aortic pseudoaneurysm have been described following penetration of the filter legs into the aortic wall [24]. This high incidence of penetration might be related to the filter design. The filter arms have pointed sharp ends and no hooks. As the filter legs anchor to the wall of the vena cava, the arms abut the wall of the cava. We propose that a change in the caval diameter for any reason could result in penetration of the caval wall by the sharp ends of the filter arms. Further studies are required to support this hypothesis.

Previous studies have shown high retrieval rates of the optional filters [13–15, 25, 26]. In our study, retrieval was attempted only in a small number of patients. This might be due to loss of patients to follow-up or to the reluctance of referring physicians to subject the patient to another procedure when there were no symptoms. The “Recovery” filter can be left *in situ* as a permanent filter. However, we found that components of the device fractured and we observed caval wall penetration in several instances. Thus, additional studies will be necessary to determine the long-term safety of the device.

There are certain limitations to our study. Imaging follow-up was not available in all patients. The penetration of caval wall by the filter legs was not verified pathologically. In addition, the study is based on the current generation of “Recovery” filter and a new generation of the filter has been introduced recently. More than half of our patients received the filter as a prophylaxis against PE. Although this is an accepted indication for filter placement in a high-risk group of patients, it is very difficult to assess the effectiveness of the filter in this group of patients. However, multiple reports show a 10–12% incidence of DVT and 1–3% incidence of PE in a high-risk group of patients in spite of thrombo-prophylaxis [27, 28]. There was no documented PE in our group of patients with level-3 trauma when the filter was placed prophylactically.

Conclusion

There was no fatal PE in our group of patients following “Recovery” filter placement. We found a high incidence of asymmetric deployment of the filter legs, fractures of the device, and asymptomatic caval penetration by the filter arms.

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EXHIBIT B

Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration

Jeffrey E. Hull, MD, and Scott W. Robertson, PhD

PURPOSE: To report on the evaluation and management of Bard Recovery filter limb perforation, fracture, and migration.

MATERIALS AND METHODS: In 2007, all patients who received a Bard Recovery filter at a single institution were contacted for consultation and evaluation by noncontrast computed tomography. Rates of limb perforation, fracture, and migration were evaluated on early (<180 days) and final images. Retrieval success and complications were evaluated.

RESULTS: Fourteen of 16 patients with Bard Recovery filters were evaluated. The early images in nine patients (mean, 30 days; range, 0–126 d \pm 40) demonstrated arm perforations in 56% ($n = 5$), leg perforation in 11% ($n = 1$), and no early fractures or migrations. Final images (mean, 899 days; range, 119–1,218 d \pm 320) demonstrated filter arm perforations in all 14 patients. Leg perforations were seen in 36% of patients ($n = 5$), and there were a total of four fractures with migration in 21% of patients ($n = 3$). All fractures occurred in arms that had perforated the vena cava on early images. Two patients had already had their filters retrieved at 119 and 302 days, respectively; the remaining 12 patients elected to have their filters retrieved after evaluation. All 12 filters were retrieved at a mean of 1,021 days (range, 119–1,242 d \pm 134). Leg hook fractures occurred during eight of 12 filter retrieval procedures (67%).

CONCLUSIONS: Recovery filter limb perforation of the vena cava increases over time and is associated with a 21% incidence of filter arm fracture and migration. Follow-up imaging is recommended. Filter retrieval has a high success rate and is the authors' preferred management strategy.

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Abbreviation: IVC = inferior vena cava

THE Recovery filter (Bard Peripheral Vascular, Tempe, Arizona) was developed as a permanent and retrievable filter and was commercially available from April 2003 to October 2005. Reports on the early experience with the Recovery filter noted problems with

arm fracture and migration (1). In 2005 the G2 filter (Bard Peripheral Vascular) replaced the Recovery filter. The new G2 filter was modified to reduce filter tilt, fracture, and migration (2). Despite the initial concerns, there is little information published in the literature on long-term outcomes with the Recovery filter.

A patient presented to our institution with symptomatic filter arm fracture and migration 2 years after placement of a Recovery filter. This patient was having chest pain and nonsustained ventricular tachycardia. The filter fragments were removed from the heart and the remaining filter was removed from the vena cava (3). A separate case report (4) describes a patient with Recovery filter arm migration to

the right ventricle resulting in right ventricle perforation and cardiac tamponade. As a result, we reviewed the records and available images in patients treated with the original Recovery filter to evaluate the incidence of inferior vena cava (IVC) arm perforation, arm fracture, and migration. All known patients were subsequently contacted for consultation and further evaluation with noncontrast computed tomography (CT). This report details the imaging findings and the resulting patient management.

MATERIALS AND METHODS

The institutional review board approved this study. Retrospective review of procedure logs, picture archiving and

From the Vascular Center (J.E.H.), Chippenham and Johnston Willis Medical Center, 7101 Jahnke Road, Richmond, VA 23225; and Nitinol Devices and Components (S.W.R.), Fremont, California. Received February 17, 2008; final revision received and accepted September 29, 2008. Address correspondence to J.E.H.; E-mail: hull.jeffrey@hcahealthcare.com

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Indications for Filter Placement (N = 16)

Indication	Incidence (%)
Anticoagulation contraindication	4 (25)
Anticoagulation complication	1 (6)
Prophylaxis	4 (25)
Prophylaxis with anticoagulation	7 (44)
Device failure	0 (0)
Associated with procedure	0 (0)
Placed with Intended removal	15 (94)

communication system images, and purchasing and billing records was performed to identify patients treated with the Recovery filter. These records revealed 16 patients with the Recovery filter. Fifteen filters were placed with intention for retrieval; one filter was placed as a permanent filter. The mean age of patients was 45 years \pm 11 (SD; range, 26–68 y). Seven filters (44%) were placed in male patients and nine (56%) were placed in female patients. Indications for filter placement are listed in the **Table**. All available images were reviewed for filter limb perforation, fracture, and migration. The number of limbs perforating the vena cava, fractured, or migrated was recorded for each examination. Subsequently, all patients were contacted by telephone and scheduled for consultation and follow-up abdominal CT. The number of final limb perforations, fractures, and migrations were obtained from follow-up CT or IVC images before filter removal. The patients' medical records were reviewed for age, sex, indication for filter placement, and symptoms related to filter fracture or migration. At follow-up consultation, the patient's current need for an IVC filter was assessed. They were advised that the Recovery filter was designed for removal, that their filter was placed with the intention of retrieval, and that the Recovery filter had been found to have arm fracture and migration in as many as 10%–20% of patients with arm perforation. Patients were then notified if they had arm perforation, fracture, or migration. In patients with filter fracture, removal was recommended. Patients with arm perforation were given the option of filter removal or regular imaging follow-up. Filter retrievals were performed in the angiography suite from the jugular approach with use of the Recovery Cone catheter (Bard Pe-

ripheral Vascular). All filters retrieved were examined with a dissecting microscope (magnification \times 50) to evaluate the location of fracture. If present, fracture surfaces were evaluated at high magnification with a scanning electron microscope to determine the fracture mechanism.

Definitions

IVC limb perforation.—A filter limb was considered to have perforated the IVC when the inferior tip of a limb was clearly outside the circumference of the vena cava on abdominal CT or an inferior vena cavogram (**Fig 1**).

Indication for filter placement.—The six indications for filter placement described by the Vena Caval Filter Consensus Committee (5) are listed in the **Table**.

Early images.—Early images are abdominal CT scans or inferior cavograms of the filter obtained less than 180 days after filter placement.

Final images.—Final images are abdominal CT scans or inferior cavograms obtained at the time of follow-up consultation or filter removal.

Spontaneous filter retrieval.—Filters removed from patients without concern for perforation, fracture, or migration were considered to have been removed spontaneously.

Complications.—Complications included pulmonary embolus, deep vein thrombosis, whole filter migration, limb perforation of IVC, limb fracture and migration, IVC thrombosis, filter tilting, IVC perforation after removal, and incomplete retrieval of the filter.

Extreme filter tilting.—Filter tilting to such an extent that the cap of the filter was in contact with the wall of the IVC was considered to constitute extreme filter tilting.

Distal attachment hook fracture.—Distal attachment hook fracture is sim-

ply fracture of the distal leg hook from the filter during filter retrieval.

Data Collection and Analysis

Data were collected as described, and quantitative analysis comparing the number of patients with perforation, fracture, and migration was performed, along with the total numbers of each. Whole filter migration, filter tilting, and IVC thrombosis rates were obtained from final images. A best estimate of time to fracture was obtained by evaluation of images between filter placement and fracture identification. Images reviewed were those available on our picture archiving and communications system. Rates of spontaneous filter retrieval and retrieval for arm perforation or fracture were calculated. Success rate, complications, fluoroscopy time, and contrast agent use during retrieval were obtained from reports. History of previous and ongoing thromboembolic disease was determined from follow-up consultation (ie, history and physical examination), available medical records on the hospital information system, and available imaging. Statistical comparisons of arm and leg perforation and fracture rates between early and final imaging was performed with use of a paired Student *t* test.

RESULTS

On initial review, nine of 16 patients had early images (range, 0–126 days \pm 40; mean, 30 d), including one patient presenting with arm fracture and migration to the right ventricle. All these patients had CT examinations of the abdomen. All filters appeared to be centered within the IVC without filter tilting. The early images demonstrated arm perforations in 56% of patients (*n* = 5), leg perforation in 11% (*n* = 1), and no early fractures or migrations. There were 12 arm perforations in five patients and one leg perforation in one patient.

At time of initial review, four patients had final images. Two patients had spontaneous removal of intact filters at 119 and 302 days, respectively, and their final images were IVC images before filter removal. Two other patients had recent abdominal CT examinations demonstrating filter arm fracture with migration and under-

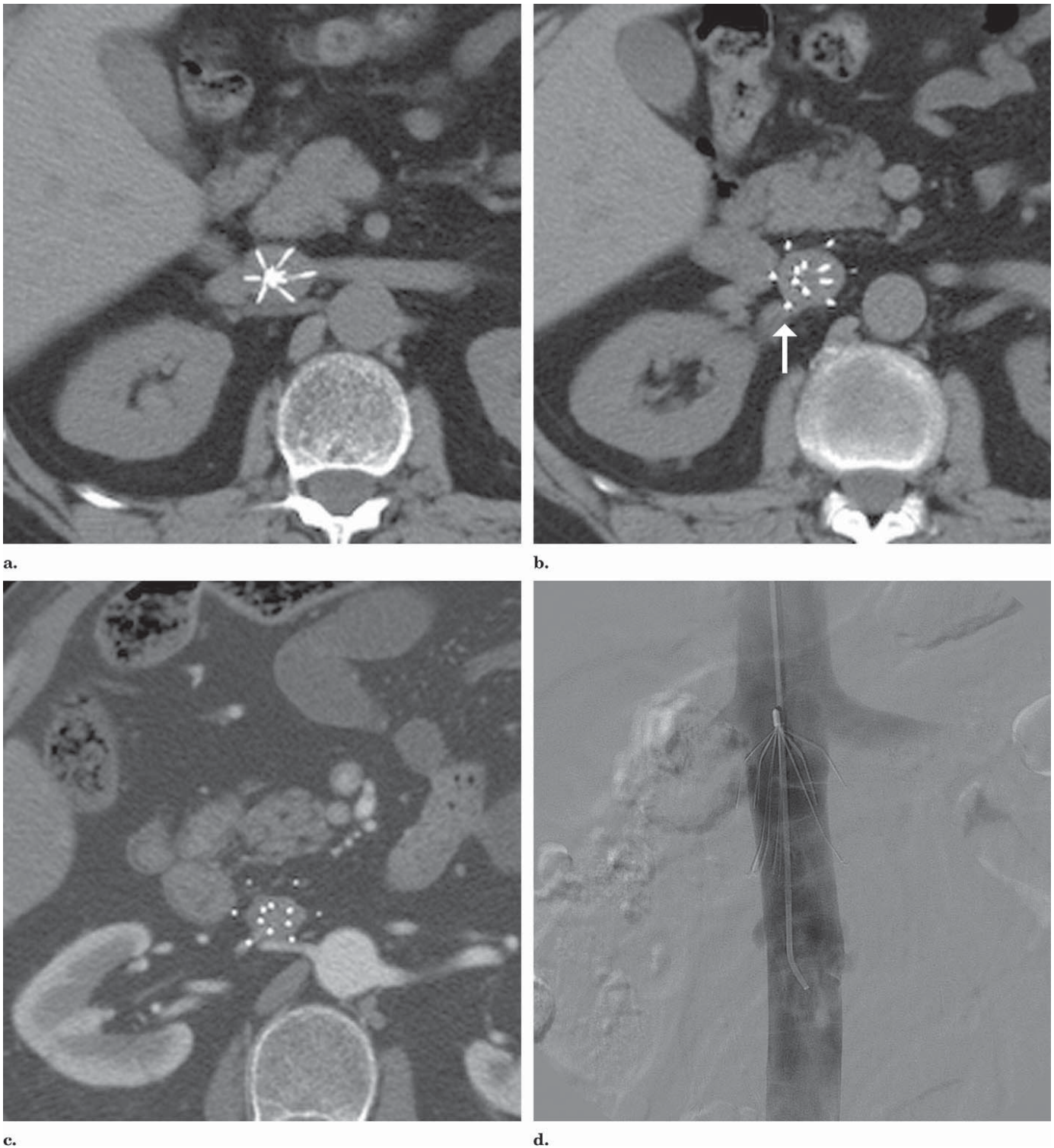


Figure 1. Appearance of perforated arms on CT and inferior vena cavogram. The Recovery filter has six arms and six legs. **(a)** Intact top of the filter with six arms. On images **(b)**, note that all the arms are outside the IVC. Several of the arms are completely surrounded by fat. The arm at 7 o'clock (white arrow) appears to be in a small vein. The six legs are in the center of IVC and none of the legs have perforated the IVC. **(c)** On an image taken caudal to **b**, the tips of only four arms are noted. Arms at 5 and 7 o'clock are adjacent to but outside the IVC (note acute angle between arm and IVC wall), and these were counted as perforations. **(d)** Anteroposterior view of the IVC shows the arms on either side to be well outside the IVC.

went filter retrieval. Therefore, in our initial review, we found a 22% prevalence ($n = 2$) of filter arm fracture and migration.

Follow-up Examination

Two of 16 patients were completely lost to follow-up. Two patients had undergone spontaneous filter removal. Twelve patients were seen in consultation, and all 12 requested filter retrieval. Two patients had symptoms related to filter fracture and migration. No patients had a history of pulmonary embolus. One patient had recurrent deep vein thrombosis.

Final images (range, 119–1,218 days; mean, $899 \text{ d} \pm 320$) were available in 88% of patients (14 of 16). Of these patients, filter arm perforation was found in all 14, leg perforation in five (36%), and fracture with migration in three (21%). A total of 61 arm perforations, 10 leg perforations, four arm fractures, and four migrations were noted. Final images were abdominal CT in 12 patients and inferior vena cavograms in two. Filter arms migrated into the right ventricle, into the right upper-lobe pulmonary artery, among the legs of the filter, and into the retroperitoneum. There were no whole-filter migrations or tilted filters. One patient had evidence of IVC thrombosis and recanalization (Fig 2). No acute thrombus was noted in the IVC.

All filters were successfully retrieved without significant complications. Procedure time ranged from 9 to 24 minutes (mean, $14 \text{ min} \pm 5$). Fluoroscopy time ranged from 2 to 7.5 minutes (mean, $4.0 \text{ min} \pm 1.7$) and contrast agent dose ranged from 20 to 80 mL (mean, $30 \text{ mL} \pm 21$). Half the migrated arms ($n = 2$) were retrieved, one from the right ventricle and one from the IVC. Two migrated filter arms were not retrieved; one was left in the right upper-lobe pulmonary artery where it had been for 18 months and one was left in the retroperitoneum. One filter was retrieved via the external jugular vein because of right internal jugular vein thrombosis. One filter was retrieved from a vena cava deformed at the filter site from earlier occlusion. There was no significant extravasation of contrast medium seen on angiograms obtained after filter retrieval. Examination of the extracted filters

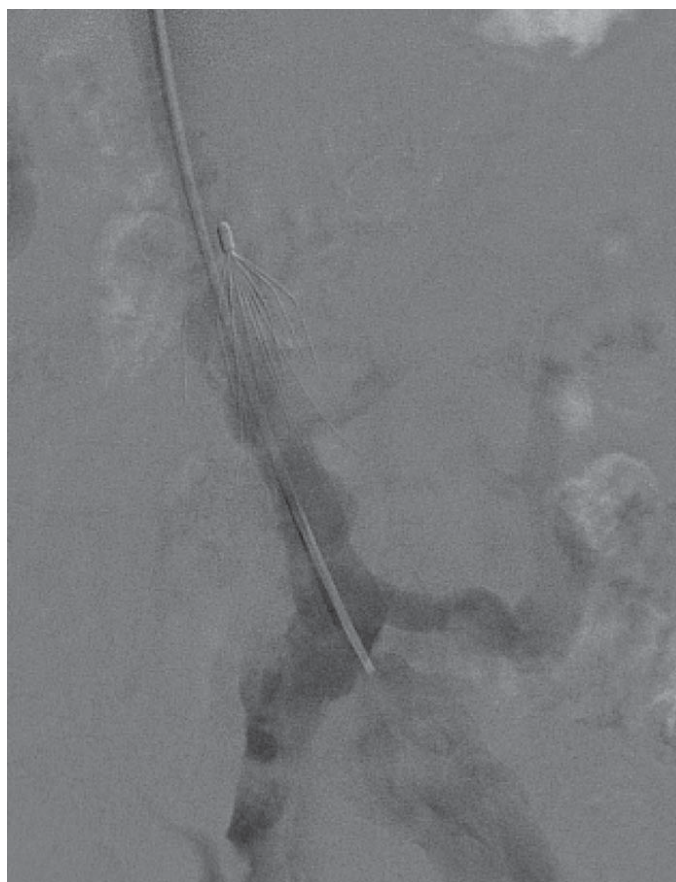


Figure 2. Narrowed and irregular IVC is seen below the Recovery filter. There is a prominent collateral vessel to the left.

demonstrated 11 distal attachment hook fractures in eight of the 12 extracted filters.

Statistical comparison of early and final images with a paired Student *t* test demonstrated significant increases in arm perforation rate over time, and a tendency—but not a statistically significant one—toward increased leg perforation and arm fractures. Early imaging (range, 0–126 days; mean, $30 \text{ d} \pm 40$) showed average per-patient rates of arm perforation of 1.33 (12 arms in nine patients), leg perforation of 0.11 (one in nine patients), and arm fracture with migration of zero. Final imaging (range, 119–1,218 days; mean, $899 \text{ d} \pm 319$) in 14 patients demonstrated higher average per-person rates of arm perforation of 4.36 (61 in 14 patients; $P = .002$), leg perforation of 0.71 (10 in 14 patients; $P = .10$), and arm fracture with migration of 0.29 (four in 14 patients; $P = .20$).

Microscopic evaluation of all four arm fractures revealed fracture just be-

low the filter cap. Furthermore, eight of the 12 retrieved filters (66%) contained fractures through the device leg's distal attachment hooks (11 total fractures). Examination of the fracture surfaces by scanning electron microscopy revealed classical signs of high-cycle metal fatigue in the fractured arms, whereas the hook fractures exhibited ductile overload fracture features with a possible low-cycle (ie, high-stress) fatigue component (6). Representative arm and hook fracture surfaces are presented in Figures 3b and c, respectively.

There was no apparent trend in the initiation site of the fatigue-fractured arms. Indeed, two fractures initiated at the outer part of the nitinol wire arm whereas the other two initiated toward the medial position of the device. However, the mechanism of fatigue fracture was evident in each fractured arm and suggested a slow fracture process resulting from the cumulative effect of cyclic deformations

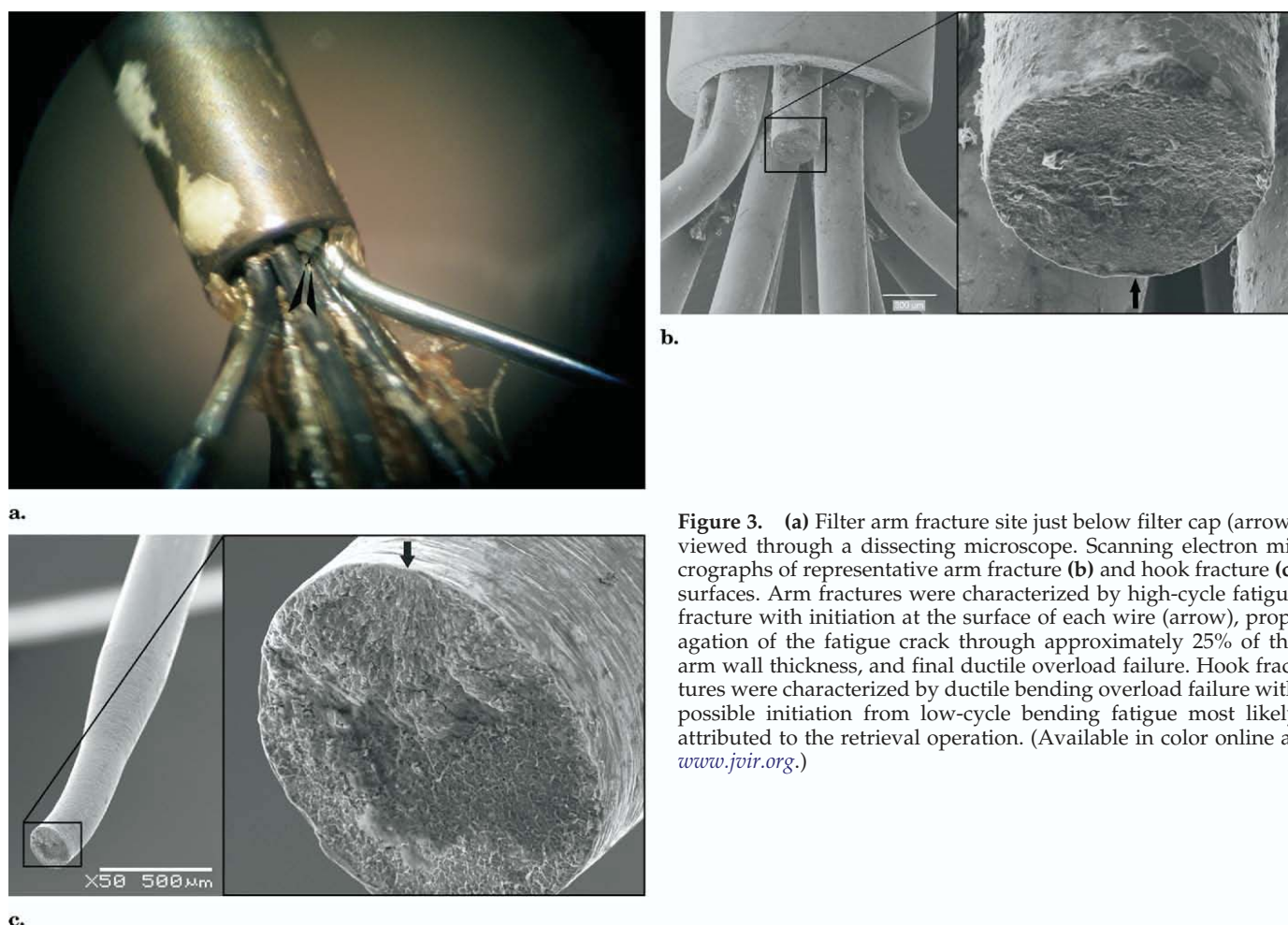


Figure 3. (a) Filter arm fracture site just below filter cap (arrow) viewed through a dissecting microscope. Scanning electron micrographs of representative arm fracture (b) and hook fracture (c) surfaces. Arm fractures were characterized by high-cycle fatigue fracture with initiation at the surface of each wire (arrow), propagation of the fatigue crack through approximately 25% of the arm wall thickness, and final ductile overload failure. Hook fractures were characterized by ductile bending overload failure with possible initiation from low-cycle bending fatigue most likely attributed to the retrieval operation. (Available in color online at www.jvir.org.)

witnessed by the device in vivo (ie, breathing). Conversely, all hook fractures were similar. They exhibited pure overload bending fractures that initiated on the concave surface of the hook. In addition, the fracture initiation sites were surrounded by rough (ie, high-energy) low-cycle fatigue features, and contained little to no tissue on the surface. It is therefore most likely that the hook fractures occurred during device the removal procedure, as the long indwell time likely promoted endothelialization of the hooks, thereby requiring significant forces to extract the devices.

DISCUSSION

Our initial review of picture archiving and communication system images of patients treated with a Recovery filter demonstrated three arm fractures and migrations in two of

nine patients with images. We believed this exceeded the previously noted fracture rate of 2%–10% outlined in the Society of Interventional Radiology consensus statement on IVC filters (7), and thus felt compelled to review our records and contact patients in whom we had placed a Recovery filter.

All the Recovery filters inserted at our institution were placed with the intention of retrieval; one patient from an outside institution had a filter placed as a permanent filter (Table). The Recovery filter was placed in a small, highly selected group of patients for whom the referring physician specifically requested a removable filter. Despite this strong bias in favor of retrieval, we found that only 13% of our patients ($n = 2$) had returned for filter removal. This low rate of retrieval is similar to the 13% reported by Grande et al (8) in 105 pa-

tients who had filters placed with the intention of retrieval. However, we found our patient population was receptive to returning for follow-up consultation and examination of their filters. All counseled patients elected to have their filter removed in part because there was a preexisting expectation that the filter would be removed and in part because they were informed that there was a potential for fracture and migration.

According to the Society of Interventional Radiology quality improvement guidelines (7), vena cava perforation is a trackable event with reported rates as high as 40%. In the current study, the incidence of Recovery filter arm perforation progressed from 56% of patients on early images (mean, 30 days \pm 40) to 100% of patients on final images (mean, 899 days \pm 320). In the same interval, fractures progressed from an incidence of

zero to 21% (four arms in three of 14 patients).

One published report (1) showed 28% of patients (11 of 40) with arm perforation at 80 days. Conversely, Binkert et al (9) reported only two limb perforations and no fractures in 13 patients at an average of 254 days. However, these authors described arms of the filter extending outside the wall of the IVC in 12 of 13 patients (92%) on inferior vena cavograms at the time of removal. The authors described this finding as “tenting the vena cava” (9). In our experience, arms extending outside the IVC wall on venograms had clearly perforated the IVC on CT images when both studies were available (**Fig 1**). Therefore, we considered arm extension beyond the IVC wall a perforation. Our study further finds a significant increase in the rate of arm perforation from early to final images.

In the present study, all fractures occurred in arms that had previously shown perforation of the IVC. Three of our 14 patients (21%) exhibited device fracture and migration. The association of fracture with previous arm perforations has been noted in a case report and an earlier study (1,3). Kalva et al (1) described 11 arm perforations with three fractures. Fractures have been reported to occur in as many as 7.5% of patients in previous studies (1,8,9), which evaluated filters at 80–254 days. The average estimated time to fracture in our study was 668 days. The current study finding of a 21% fracture prevalence may be related to longer follow-up interval.

All fractured arms migrated. Two migrations were local: one migrated into the adjacent retroperitoneum and one moved into the legs of the filter. These local migrations were thought to be asymptomatic. Two of our patients were symptomatic; one had persistent symptoms of chest pain and nonsustained ventricular tachycardia to the extent that we were obliged to uncover the underlying source. The other patient had transitory symptoms after right pulmonary artery migration. This patient came to the hospital with atypical chest pain; the patient was evaluated and discharged after negative findings on a workup that included chest radiography (**Fig 4**). The migrated filter arm was discov-



Figure 4. Chest radiograph obtained in a patient with a Recovery filter who was seen in the emergency room for atypical chest pain.

ered 18 months later after we contacted the patient for follow-up.

The fractures were seen to have occurred just below the filter cap on CT images as well as on microscopic examination (**Fig 3a**). Scanning electron microscopy of the fractured arm surfaces demonstrated changes characteristic of bending fatigue fractures (**Fig 3b**). Arm fractures are apparent on abdominal CT studies (**Fig 5**), but the migrated fragments were more difficult to detect. The conspicuity of migrated arms on plain radiographs was poor, and migrated arms were difficult to find even when an arm was known to be absent from its proper location on the filter. In one case, an arm that migrated to the right upper lobe was repeatedly missed on plain radiography and CT of the chest. The difficulty in identifying the fragment on plain radiographs most likely arose from the fact that there were surgical clips nearby (**Figs 4,6**). On CT, the arm was difficult to see on axial noncontrast images. Contrast-enhanced images obscured the arm on most stan-

dard window and level settings (**Fig 6**). Assuming that our data do not represent a statistical aberration, we suggest there are many other patients with Recovery filters with arm fractures and migrations in whom it is conceivable that these migrated fragments have gone undetected.

The purpose of the retrievable filter is to reduce risk to the patient. The retrievable filter concept is built on the idea that a long-term venous foreign body is undesirable, as is demonstrated in the often-cited article by Decousus et al (10). In addition, the Recovery filter is associated with a high rate of IVC arm perforation and structural weakness, as initially reported by Kalva et al (1) in a multicenter study. The current study is in agreement with the findings of Kalva et al (1) that arm perforation and structural weakness leads to fracture. In addition, we have shown high incidences and statistically significant progression of filter arm IVC perforation rates between early and final images, suggesting that fracture rates may progress as well. A

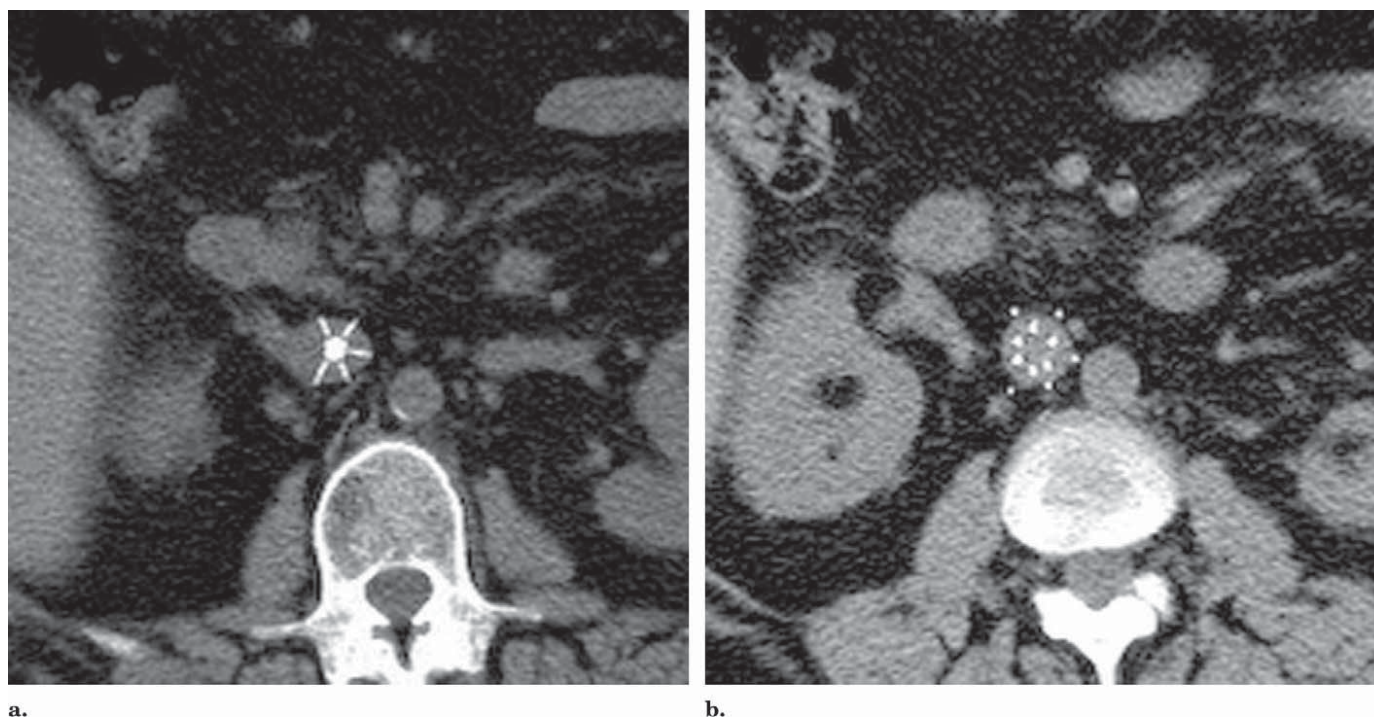


Figure 5. Abdominal CT findings of fracture. (a) At the top of the filter, the cap is in the center of the IVC. Only five arms are present (compare with Fig 1a). The arm at nine o'clock is absent. (b) The most caudal image demonstrates the tips of the remaining arms: three arms have perforated the IVC, extending beyond the IVC wall. Arms at 3 and 6 o'clock were not counted as perforations because of a lack of a clear acute angle of tissue between the arm and the IVC wall.

significant increase in fracture rates was not demonstrated in the present small series, but an arm fracture and migration rate of 21% was found. Serious clinical events associated with filter fracture and migration have been reported rarely (3,4). The overall risk of leaving the Recovery filter in place is defined by the risk of increased thromboembolic disease inherent in all filters and the risk that the high rate of arm perforation will lead to increasing numbers of fractures, migrations, and clinical events. Fortunately, the retrieval side of this analysis is better defined.

The current report demonstrated a 100% success rate for late filter retrieval at a mean of 1,014 days \pm 137. Similarly high success rates of 82%–100% for retrieval of the Recovery filter have been reported in small series of 13–24 patients (1,8,9,11,12). The range of average indwell times for these series was 33–254 days. In the series with the longest reported dwell time of 254 days in 13 patients (9), 100% of retrievals were successful. In all reports, retrievals were performed without major complication. Failed re-

trievals were related to residual thrombus or tilted filters (1,8,12). It appears the indwell time before retrieval of the Recovery filter is indefinite. The relative ease, high success rate, and low complication rate of retrieving the Recovery filter makes the decision for removal less complicated.

Based on the clinically successful filter retrieval in the limited patient population of the present study, there appears to be justification for late-stage removal of these devices. The most clinically significant reason is the potential risk of migration of a fractured arm into the heart or lungs, which could result in a negative clinical sequela; or that leaving the devices implanted exposes them to additional deformation cycles, thereby increasing the risk of arm fatigue fracture. In addition, fracture of the device exposes fresh (ie, non-passivated) metal to the blood stream, which could result in an inflammatory response in patients with nickel allergies, and/or corrosion of the device itself. However, retrieval is not without its risks. Indeed, removal of the Recovery filter resulted in leg hook fracture in 66% of patients (eight of 12). Although it

is most likely that the fractured leg hook remnants stay contained within the IVC walls, there is the possibility of migration of these small (approximately 1 mm long) fragments through the circulatory system, which poses a potential risk of embolization.

The patients with the Recovery filter did not have clinical evidence of recurrent pulmonary embolus. One patient had problems with bilateral leg swelling and recurrent deep vein thrombosis. This patient was found to have a narrowing and irregularity of the IVC at the level of the filter and a prominent collateral vein, suggesting thrombosis and recanalization of the IVC at the filter placement site (Fig 2). This patient receives permanent long-term anticoagulation. His filter was removed without complication. No other thromboembolic complications were noted in our patients. None of the filters were tilted into the wall of the IVC or exhibited significant displacement. These complications are in keeping with expected outcomes for a permanent or retrievable filter (7).

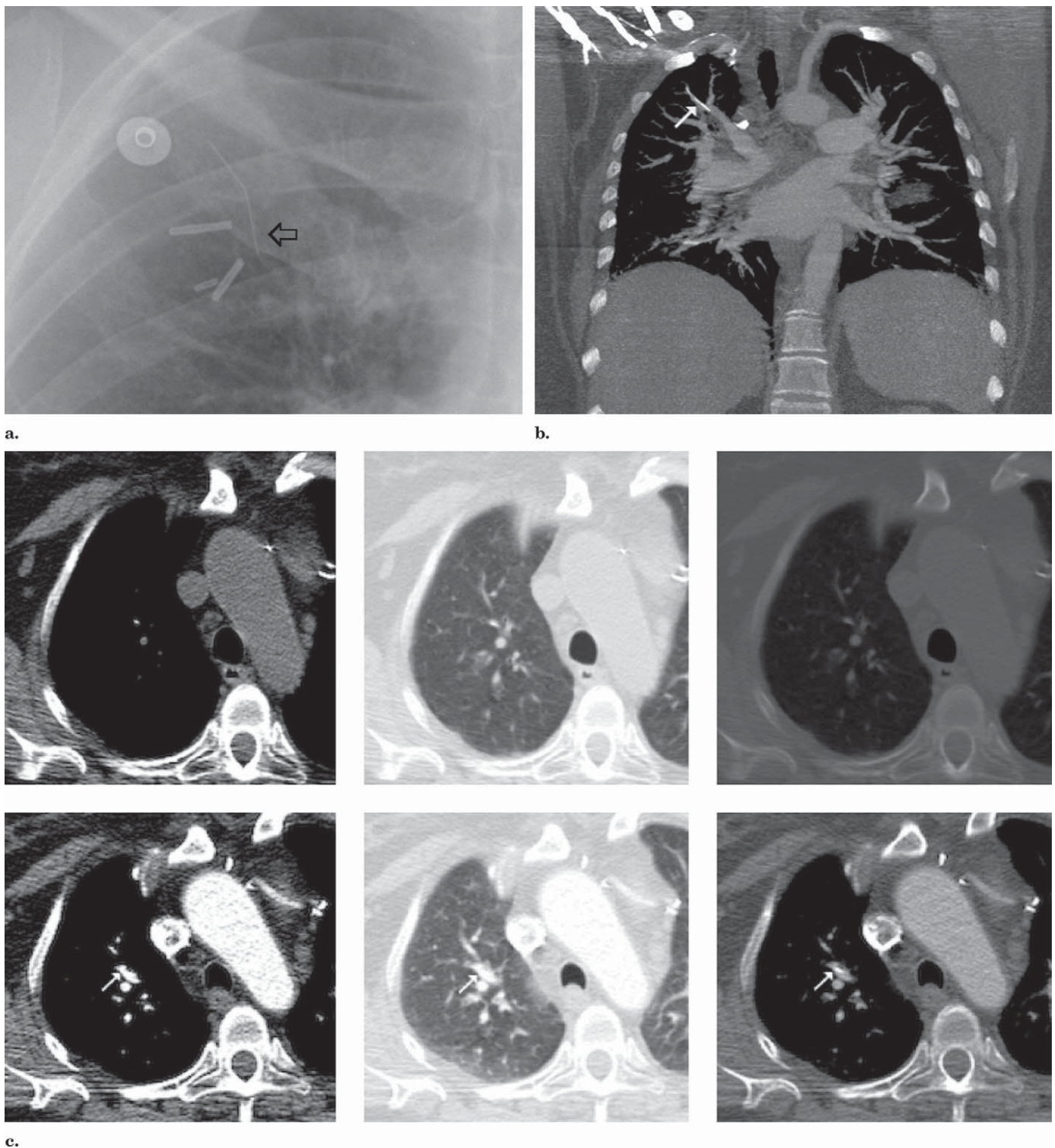


Figure 6. (a) Magnified view of right upper lobe (same as Fig 4). Migrated arm (open arrow) was missed on numerous chest radiographs and chest CT examinations over a period of 18 months. (b) Fragment in right upper lobe is seen on contrast-enhanced chest CT scan (white arrow). (c) Axial images with and without contrast medium windowed and leveled for mediastinum, lung, and bone, respectively. White arrow points to the hard-to-see filter fragment on the contrast images.

The present study has profound implications for patients with Recovery filters, suggesting that these patients require more intensive imaging and clinical follow-up; however, the patient cohort is too small to allow definitive recommendations. The study does define an important clinical problem with the Recovery filter and describes some of the clinical and imaging findings associated with filter fracture and migration. The site and type of the arm and distal attachment hook fractures has been identified, but the overall mechanism for the more clinically relevant arm fractures is still uncertain. *In situ* motion analysis could give insight into the forces causing the arms to fracture. The present study does not evaluate the risk and benefits of leaving the Recovery filter in place versus removal, as all patients underwent filter retrieval. Study of a larger number of patients with the Recovery filter is necessary to clarify the best course of action for these patients.

The Bard Recovery filter was found to be associated with increasing rates of limb perforation, arm fracture, and migration in our small study population. IVC wall perforations of the upper arm of the Recovery filter progress over time and are associated with filter arm fracture and migration. The Recovery filter has otherwise functioned well as an IVC filter. The Recovery filter appears to have an indefinite indwell time before retrieval. We are

recommending imaging with abdominal CT to screen for perforation, fracture, and migration in patients with a Recovery filter in place. In our experience, fractured filters can be removed successfully with high success rates and a low incidence of complications. Removal may be considered if the clinical risks associated with leaving the fractured device in place outweigh the risks attributed to the removal procedure.

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EXHIBIT C

In Re: Bard IVC Filters Products Liability

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters
Products Liability Litigation

No. MD-15-02641-PHX-DGC

DEPOSITION OF:
ROBERT O. RITCHIE, PhD
June 9, 2017

REPORTER'S TRANSCRIPT OF PROCEEDINGS
BY Jill Anne Stephenson, CSR 8563

In Re: Bard IVC Filters Products Liability

<p style="text-align: right;">Page 122</p> <p>1 -- is that -- what's the name of that? There's a report 2 that goes through the history of -- it's by a woman who 3 used to work for the FDA. 4 Q. Oh, Parisian? 5 A. Parisian, that's right. There's a comment in 6 there about that. 7 Q. Oh. I'm just wondering -- she's an expert in 8 the case. I'm just wondering whether you're aware of 9 any medical study that talks about that. 10 A. No. 11 Q. Okay. Do you -- have you looked at all at the 12 issues of whether electropolishing has any impact on 13 tilt? 14 A. No, I haven't. One could conceive that the 15 smoother surface may have somewhat less a frictional 16 resistance at the site of the vena cava, but between you 17 and me, I don't think it would have any effect at all. 18 Q. How about the Meridian and Denali additions of 19 the anchors relative to tilt? Do you think that could 20 have had an impact on improving -- 21 A. I can't remember, but they certainly would have 22 had an impact, but I don't recall the statistics of what 23 that was. 24 Q. Okay, and you haven't studied the mechanism by 25 which they might or might not improve tilt.</p> <p style="text-align: right;">DEPOSITION OF {} 122</p>	<p style="text-align: right;">Page 124</p> <p>1 Q. So a given -- a given tilt may result in 2 perforation, true? 3 MR. DALIMONTE: Objection. 4 THE DEPONENT: Of course. 5 Q. (By Ms. Daly) Okay. But you have not been 6 able to drill down to determine what degree of tilt, for 7 example, would result in what perforation or where in 8 the filter; is that fair? 9 A. Yeah, but there's so many other variables that 10 are involved, so it would be difficult to do that 11 precisely, but no, I haven't done that. 12 Q. And have you done any work to determine the 13 probability of perforation in the face of any particular 14 degree of tilt? 15 A. I haven't done that, no. 16 Q. Do you know if that's ever been studied in the 17 literature? 18 A. Not to my knowledge. I mean, you've got the 19 statistics of the failures where you could sort of piece 20 something together. And if you looked at some of 21 McMeeking's calculations, you might be able to say, 22 "Well, certain scenarios would give rise to a higher 23 stress and therefore likely to be a higher probability," 24 but I don't think there's any definitive studies on it. 25 You could do a definitive study on it.</p> <p style="text-align: right;">DEPOSITION OF {} 124</p>
<p style="text-align: right;">Page 123</p> <p>1 A. You know, peripherally they have these little 2 -- doesn't the Denali have a little plate -- these 3 things could all influence it. I haven't done a precise 4 study on it. 5 Q. Now let's talk about tilt as it relates to 6 perforation for a moment. What do you rely on to opine 7 that tilt can lead to perforation? 8 A. Well, again, it's -- there's a series -- 9 McMeeking has done calculations on this and has certain 10 theories, but my feeling on this has been that -- that 11 there's a linkage with some -- with migration as well. 12 Some degree of tilt means that you have an 13 anchor that's not anchored, and that means that the 14 ability of the filter to move is obviously elevated 15 because you're not fully anchored. Once the filter 16 starts to move, the probability of perforation is 17 likely, and all these things relate to the possibility 18 of fracture and -- 'cause that's what we talked about 19 earlier with the crack growing in different directions. 20 So I've -- I've always seen this as what I call 21 a vicious circle. It's a synergy of events. And I 22 think what McMeeking has been able to do is to show that 23 some of these scenarios and details are in here will 24 elevate the stresses and so forth. So all this seems to 25 be a reasonably consistent picture.</p> <p style="text-align: right;">DEPOSITION OF {} 123</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. You don't think you could or -- 2 MR. DALIMONTE: Objection. 3 THE DEPONENT: It would be very difficult. 4 Q. (By Ms. Daly) Okay. Have you looked at all at 5 the issue of tilt in non-Bard filters? 6 A. Peripherally with the Cook filters. 7 Q. Are you familiar with, for example, Durax' 8 study of the Tulip and Celest filters? 9 A. Yeah, I've looked at that. I don't recall the 10 detail, but I've looked at that. 11 Q. His finding was 30 percent of Tulips tilting 12 and 48 percent of Cooks tilting. Does that -- 13 A. Yeah. 14 Q. Do you recall that? Are you also familiar with 15 the Chou, C-h-o-u, study of Cook Celest showing a 73 16 percent tilt, 73 percent of filters tilting -- 17 A. Yeah, I did a Cook report some time ago and I 18 remember those things. I haven't looked recently. 19 Q. All right. Let's talk just a little more about 20 perforation. We've talked a good bit about that. Have 21 you looked at medical literature about the 22 susceptibility or lack thereof of perforation in Bard 23 filters? 24 A. I've seen papers, yes, that talk about that, 25 yes.</p> <p style="text-align: right;">DEPOSITION OF {} 125</p>

In Re: Bard IVC Filters Products Liability

<p style="text-align: right;">Page 154</p> <p>1 the device that it was modifying under the FDA 15K?</p> <p>2 A. I'm aware of that, yes.</p> <p>3 Q. So they had to represent to the FDA that the</p> <p>4 Recovery filter was safer and more effective than the</p> <p>5 Simon Nitinol filter, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And it had to be the substantial equivalent?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And is it your opinion, to a reasonable</p> <p>10 degree of scientific and engineering certainty, and your</p> <p>11 familiarity with the Bard IVC filter line -- was the</p> <p>12 Recovery filter safer and more efficacious than the</p> <p>13 Simon Nitinol filter?</p> <p>14 A. Well, the -- you know, as I understood the</p> <p>15 situations with respect to adverse events, that doesn't</p> <p>16 seem to be borne out by the data. I have a personal</p> <p>17 opinion on this as well. I think --</p> <p>18 Q. Let's just stick to the question.</p> <p>19 A. Okay, but --</p> <p>20 Q. Hold on. So you're aware that the Simon</p> <p>21 Nitinol filter is a permanent filter.</p> <p>22 A. I am, indeed.</p> <p>23 Q. And the Recovery filter was also a permanent?</p> <p>24 A. Initially, yes.</p> <p>25 Q. And it's still -- the Recovery, G2, the G2-X,</p> <p style="text-align: center;">DEPOSITION OF {} 154</p>	<p style="text-align: right;">Page 156</p> <p>1 design, with a few little differences I've talked about.</p> <p>2 So it's hard to believe that there would be radical</p> <p>3 changes in the function that caused the problems.</p> <p>4 Now, obviously, the fact that after the</p> <p>5 Eclipse, that the electropolish, that will alleviate one</p> <p>6 aspect. But you don't need to actually touch one, but I</p> <p>7 -- you know, when it comes to looking at fracture, I</p> <p>8 like to be able to see a fracture mode, so it's nice to</p> <p>9 be able to have the part. But from the perspective of</p> <p>10 do I expect this to have a similar set of problems or</p> <p>11 something like that, you don't really need to see it for</p> <p>12 that reason.</p> <p>13 Q. Well, you talked about what you do, what you</p> <p>14 teach and what you do for the industry.</p> <p>15 A. Yeah.</p> <p>16 Q. And if there are certain failure modes being</p> <p>17 reported, you know there's a problem.</p> <p>18 A. Yeah. I'm mean, I work on nuclear graphite,</p> <p>19 but I don't crawl on nuclear reactors just to be able to</p> <p>20 get my hands on them. Obviously, an experimentist likes</p> <p>21 to see something, but it's not an essential thing.</p> <p>22 Q. It just provides that added confidence, right?</p> <p>23 A. But, I mean, when you're looking at fractures,</p> <p>24 it's nice to have looked at the fracture. But, yes, of</p> <p>25 course, something.</p> <p style="text-align: center;">DEPOSITION OF {} 156</p>
<p style="text-align: right;">Page 155</p> <p>1 the Meridian -- or the Eclipse, the Meridian and the</p> <p>2 Denali are all permanent filters with the option to</p> <p>3 retrieve them?</p> <p>4 A. Correct, yes.</p> <p>5 Q. So they're all permanent filters.</p> <p>6 A. Yes.</p> <p>7 Q. So would it be fair to say the Simon Nitinol</p> <p>8 filter is the safer alternative among the other filters?</p> <p>9 MS. DALY: Object to form. Lack of foundation.</p> <p>10 THE DEPONENT: Yeah, I mean, I only have -- I</p> <p>11 can just recall looking at failure rates and so forth,</p> <p>12 and certainly the Recovery in G2s seem to have more</p> <p>13 problems than the Simon Nitinol filter.</p> <p>14 Q. (By Mr. Dalimonte) So your answer is "yes"?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Do you need to actually conduct a bench</p> <p>17 test to determine that there's the Bard IVC filter line,</p> <p>18 the Recovery G2, Eclipse, and stick with the Meridian,</p> <p>19 are defectively designed?</p> <p>20 A. Well, it's -- it's -- I mean, essentially no,</p> <p>21 but it's nice to have -- it's always good -- I'm an</p> <p>22 experimentist. I like to look at something, right? And</p> <p>23 I'm having to rely on reading documents and so forth</p> <p>24 about the design, but certainly the G2, G2 Express, the</p> <p>25 Eclipse and the Meridian have an essentially similar</p> <p style="text-align: center;">DEPOSITION OF {} 155</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. And without actually conducting a bench test,</p> <p>2 that doesn't affect your opinion to -- any of your</p> <p>3 opinions to a reasonable degree of scientific and</p> <p>4 engineering certainty, correct?</p> <p>5 A. A bench test would be a tested device, right?</p> <p>6 Q. I'm sorry, what?</p> <p>7 A. A bench --</p> <p>8 Q. Yes, yes, correct. So let me repeat the</p> <p>9 question so the record is clear.</p> <p>10 You do not need to conduct a bench test --</p> <p>11 well, a bench test, lack of a bench test -- well, strike</p> <p>12 that, 'cause I asked the question perfectly the first</p> <p>13 time.</p> <p>14 Your opinions, to a reasonable degree of</p> <p>15 scientific and engineering certainty, are not affected</p> <p>16 in any way by the fact that you personally didn't do any</p> <p>17 type of bench tests, correct?</p> <p>18 A. No.</p> <p>19 Q. Is that right?</p> <p>20 A. That's right, yeah.</p> <p>21 Q. And you also had the benefit of reviewing all</p> <p>22 of the tests that Bard did on their filters, correct?</p> <p>23 A. Yeah, I've looked at all of them at some time</p> <p>24 over the last several years.</p> <p>25 Q. And you testified earlier to Ms. Daly's</p> <p style="text-align: center;">DEPOSITION OF {} 157</p>

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<p style="text-align: right;">Page 158</p> <p>1 questions as to what Bard needed to do as far as</p> <p>2 matching their bench test results, which were coming</p> <p>3 back with this filter's passing, with real life problems</p> <p>4 that are being reported, you know, to the FDA, to the</p> <p>5 manufacturer about failures and adverse events</p> <p>6 associated with their product.</p> <p>7 A. Well, I think the bench tests that a company</p> <p>8 develops before and during the process of selling their</p> <p>9 component, whatever it may be, if they're suffering</p> <p>10 adverse events in practice, then they need to find the</p> <p>11 source of that and they need to find a bench test that</p> <p>12 can simulate it.</p> <p>13 I think doing bench tests which -- which were</p> <p>14 their components largely pass and yet the reality is</p> <p>15 that they're failing in practice, there's something</p> <p>16 wrong with that picture. So I've been critical of a lot</p> <p>17 of the tests that Bard did, because they never had a</p> <p>18 failure.</p> <p>19 Q. Give me a minute. I might be done. Can we go</p> <p>20 off the record?</p> <p>21 VIDEOGRAPHER: We're off the record at 2:47</p> <p>22 p.m.</p> <p>23 (Recess)</p> <p>24 VIDEOGRAPHER: We are back on the record. The</p> <p>25 time is 2:51 p.m.</p> <p style="text-align: right;">DEPOSITION OF {} 158</p>	<p style="text-align: right;">Page 160</p> <p>1 Q. And you're aware that they did testing where</p> <p>2 they tilted a filter to see would happen to it --</p> <p>3 A. Yes.</p> <p>4 Q. -- and that they tested a filter until they</p> <p>5 could make it migrate.</p> <p>6 A. Yes, but -- and that was good, but, you know,</p> <p>7 they -- to my way of thinking, they had sort of -- they</p> <p>8 -- they chose, for example, for migration, to lower</p> <p>9 pressure, and they had things that were migrating just a</p> <p>10 little bit higher pressure in their tests, and -- and</p> <p>11 yet they had a problem with migration in reality.</p> <p>12 So I think the bench tests that were done from</p> <p>13 the very beginning should have somehow sought to reflect</p> <p>14 some of the problems that they were seeing. And I think</p> <p>15 that the function of these filters was somewhat abnormal</p> <p>16 to them. And that's okay initially, because -- you</p> <p>17 know, to understand that. But there was a long history</p> <p>18 where this -- where it wasn't deal with; I think that</p> <p>19 was the issue. That's my only query about that.</p> <p>20 Q. And as we talked about before, you have not, in</p> <p>21 your role in this case, tried to fashion what those</p> <p>22 tests would be.</p> <p>23 A. Well, you know, no, that would not be my</p> <p>24 position, but I think they should have done so.</p> <p>25 Q. All right. You were asked a series of</p> <p style="text-align: right;">DEPOSITION OF {} 160</p>
<p style="text-align: right;">Page 159</p> <p>1 REDIRECT EXAMINATION BY</p> <p>2 MS. DALY: Q. Dr. Ritchie, just a couple of</p> <p>3 questions. Going back to the testing --</p> <p>4 A. Yeah.</p> <p>5 Q. -- which was the last thing Mr. Dalimonte asked</p> <p>6 you about, is it your understanding that Bard did not do</p> <p>7 testing which resulted in taking the filter to a point</p> <p>8 that it fractured or migrated or tilted?</p> <p>9 A. Well, to some degree that's true, because the</p> <p>10 medical industry works on survival rather than failure,</p> <p>11 which is not a good thing. But my main point is if you</p> <p>12 have a bench test, you need to somehow simulate the</p> <p>13 reality of your situation, which can be a path in vivo,</p> <p>14 and if you're suffering whatever it may be, tilt or what</p> <p>15 have you, you need to have a bench test that somehow</p> <p>16 reflects that.</p> <p>17 And to have a bench test where you do something</p> <p>18 and it passes every time, yet the reality is clearly not</p> <p>19 doing that, tells you that your bench test is really not</p> <p>20 reflective of the situation. So in some respects, some</p> <p>21 of those bench tests are a complete waste of time.</p> <p>22 Q. But you are aware they did testing of filters</p> <p>23 to actual failure, where they --</p> <p>24 A. Of course, yes, and that was good, that was</p> <p>25 good, but --</p> <p style="text-align: right;">DEPOSITION OF {} 159</p>	<p style="text-align: right;">Page 161</p> <p>1 questions about reasonable engineering certainties.</p> <p>2 A. Yeah.</p> <p>3 Q. Let me just -- let me clarify this in my own</p> <p>4 mind. What I think you're saying is you can not, within</p> <p>5 a reasonable engineering certainty -- hold it. Let me</p> <p>6 say this right.</p> <p>7 Okay. You can not, within a reasonable</p> <p>8 engineering certainty, say what the likelihood is of</p> <p>9 occurrence of a particular type of complication in a</p> <p>10 particular filter.</p> <p>11 A. In a particular --</p> <p>12 MR. DALIMONTE: Objection.</p> <p>13 THE DEPONENT: A given filter or a particular</p> <p>14 type of filter?</p> <p>15 Q. (By Ms. Daly) You can't say that there is an</p> <p>16 increased likelihood --</p> <p>17 A. Yes.</p> <p>18 Q. -- of complications generally.</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Also you can not say, within a</p> <p>21 reasonable engineering certainty, what the relative</p> <p>22 increased likelihood would be for any particular</p> <p>23 complication to occur in each of the various models of</p> <p>24 Bard filters.</p> <p>25 A. Well, this is difficult to answer. The -- no,</p> <p style="text-align: right;">DEPOSITION OF {} 161</p>

EXHIBIT D

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Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

IN RE: BARD IVC FILTERS :
PRODUCTS LIABILITY LITIGATION : No. MD-15-02641-PHX-DGC
: :

- - -

OCTOBER 11, 2016

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CONFIDENTIALITY REVIEW

Videotaped deposition of CHRISTOPHER
D. GANSER, held at HILTON SHORT HILLS,
41 John F. Kennedy Parkway, Short Hills, New
Jersey, commencing at 9:32 a.m., before
Margaret M. Reihl, a Registered Professional
Reporter, Certified Realtime Reporter, and
Notary Public.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

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<p>1 to be placed; is that a true statement?</p> <p>2 A. They're placed in the cava.</p> <p>3 Q. Sir, my question is real simple. You</p> <p>4 used the word intended. My question -- can I have</p> <p>5 this.</p> <p>6 If it doesn't do that, meaning stay</p> <p>7 where it's put, stop a trap from migrating to the heart</p> <p>8 and potentially causing a pulmonary embolism, then it</p> <p>9 doesn't meet the purpose for which it was intended to</p> <p>10 be placed; is that a true statement?</p> <p>11 A. It is.</p> <p>12 Q. Okay. Let me back up to some background</p> <p>13 stuff. You were a vice president of quality assurance,</p> <p>14 I believe, from 2003 to 2007, true?</p> <p>15 A. I believe my title at the time was vice</p> <p>16 president of regulatory sciences, which included</p> <p>17 quality assurance.</p> <p>18 Q. Tell the jury what regulatory sciences</p> <p>19 is.</p> <p>20 A. Regulatory sciences are the -- is a</p> <p>21 department that manages the functions of quality</p> <p>22 assurance, regulatory affairs and medical affairs at</p> <p>23 C.R. Bard.</p> <p>24 Q. So you oversaw as vice president quality</p>	<p>1 A. Occasionally.</p> <p>2 Q. Was he someone whose opinions you</p> <p>3 respected while you worked with him?</p> <p>4 A. Yes.</p> <p>5 Q. Okay so if Doug Uelman had determined</p> <p>6 that any Bard product had an unacceptable or an</p> <p>7 unreasonable risk, would you accept that opinion from</p> <p>8 Doug Uelman?</p> <p>9 A. If it was substantiated with appropriate</p> <p>10 data.</p> <p>11 Q. Okay. And you would take Doug Uelman's</p> <p>12 opinion regarding unacceptable or unreasonable risk</p> <p>13 seriously, wouldn't you?</p> <p>14 A. I would take it very seriously.</p> <p>15 Q. So as the corporate person at C.R. Bard</p> <p>16 who was working with the Peripheral Vascular person in</p> <p>17 quality assurance, what was your -- what were your</p> <p>18 duties, in other words, what did you do?</p> <p>19 A. As the head of --</p> <p>20 Q. Quality assurance.</p> <p>21 A. -- quality assurance, I was primarily</p> <p>22 responsible for ensuring that there was a corporate</p> <p>23 quality system established, that individuals at the</p> <p>24 divisions executed that quality system with their own</p>
Page 15	Page 17
<p>1 assurance, regulatory affairs and medical affairs at</p> <p>2 C.R. Bard from 2003 to 2007; is that correct?</p> <p>3 A. I have to refresh my memory so excuse</p> <p>4 me. I think from 2003 to 2005 that is true, and I</p> <p>5 think after 2005 the regulatory affairs function</p> <p>6 reported directly to the CEO, and I believe the medical</p> <p>7 affairs function, as part of a reorganization, reported</p> <p>8 to the head of science and technology.</p> <p>9 Q. Okay. So let's talk about the time</p> <p>10 period 2003 and 2005.</p> <p>11 Did the head of quality assurance report</p> <p>12 to you?</p> <p>13 A. I was the head of quality assurance for</p> <p>14 C.R. Bard.</p> <p>15 Q. Was there a quality assurance person at</p> <p>16 Bard Peripheral Vascular that reported to you?</p> <p>17 A. There was.</p> <p>18 Q. Who was that?</p> <p>19 A. In 2003 till I believe till May 2005</p> <p>20 that was Doug Uelman.</p> <p>21 Q. Do you still know Doug Uelman?</p> <p>22 A. I do.</p> <p>23 Q. Do you still stay in touch with Doug</p> <p>24 Uelman?</p>	<p>1 divisional policies and procedures consistent with the</p> <p>2 corporate policies and consistent with the regulations</p> <p>3 that needed to be followed for the design development</p> <p>4 manufacturing of the devices for that division.</p> <p>5 I was responsible for making sure that</p> <p>6 the divisions were adequately staffed with quality</p> <p>7 assurance personnel.</p> <p>8 Q. Okay.</p> <p>9 A. I was also responsible for, I believe at</p> <p>10 the time, the audit function for compliance of the</p> <p>11 quality system requirements and procedures.</p> <p>12 Q. Where were you officed in 2003 through</p> <p>13 2007?</p> <p>14 A. In Murray Hill, New Jersey.</p> <p>15 Q. Is that where Mr. Ring and Mr. Weiland</p> <p>16 are also officed?</p> <p>17 A. Yes.</p> <p>18 Q. Mr. Barry was he here then too?</p> <p>19 A. Mr. Barry joined Bard in August of 2003,</p> <p>20 yes.</p> <p>21 Q. How about Jen Schulz, was she in New</p> <p>22 Jersey?</p> <p>23 A. No, Jen was in Tempe, Arizona.</p> <p>24 Q. As head of quality assurance, did you</p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 70</p> <p>1 Do you see where I am?</p> <p>2 A. Yes.</p> <p>3 Q. Number one doesn't apply. Well,</p> <p>4 protective wear would be if you're in surgery, you have</p> <p>5 to wear gloves, but let's focus on this second hash --</p> <p>6 dash, "Identify any laboratory tests or other</p> <p>7 evaluations that may be helpful in following the</p> <p>8 patient's response or in identifying adverse reactions</p> <p>9 and, if appropriate, specify the frequency of such</p> <p>10 tests or evaluations before, during and after use of</p> <p>11 the device."</p> <p>12 Did I read that correctly?</p> <p>13 A. Yes.</p> <p>14 Q. And did Bard ever do that with its</p> <p>15 Recovery, its G2, Eclipse or any of the IVC filters,</p> <p>16 recommend any special testing in response to the</p> <p>17 adverse reactions that that device was experiencing?</p> <p>18 A. Recommend any special testing to the</p> <p>19 clinicians -- to the clinicians?</p> <p>20 Q. Any precaution for any test or</p> <p>21 evaluations that may be helpful in identifying adverse</p> <p>22 reactions.</p> <p>23 A. I don't think Bard recommended any</p> <p>24 laboratory tests or any other evaluations that may</p>	<p style="text-align: right;">Page 72</p> <p>1 tilting at 15 degrees or more could result in those</p> <p>2 issues, the company never told doctors or patients that</p> <p>3 they ought to have their device evaluated to make sure</p> <p>4 that it was staying perfectly centered, did they?</p> <p>5 A. I can't recall they did.</p> <p>6 Q. Don't you think they should have?</p> <p>7 A. If we knew there was a direct</p> <p>8 correlation with tilting and the increase of risk and</p> <p>9 harm, yes.</p> <p>10 Q. Okay. And, also, tilting can beget more</p> <p>11 tilting right? In other words, as soon as it starts to</p> <p>12 tip over, sometimes it's like Humpty-Dumpty, right, all</p> <p>13 of the sudden it will just fall; it can go all the way</p> <p>14 down and lay sideways?</p> <p>15 MS. DALY: Object to the form, lack of</p> <p>16 foundation.</p> <p>17 MR. LOPEZ: Let me withdraw that</p> <p>18 question, take out the Humpty-Dumpty part. It</p> <p>19 wasn't a good metaphor anyway. I could have</p> <p>20 done better than that.</p> <p>21 BY MR. LOPEZ:</p> <p>22 Q. My point is once a device starts to tilt</p> <p>23 5 degrees, 10 degrees, 15 degrees, I mean, that could</p> <p>24 be the starting point of the device tilted even more</p>
<p style="text-align: right;">Page 71</p> <p>1 identify adverse reactions.</p> <p>2 Q. Okay.</p> <p>3 A. Other than what was in the current</p> <p>4 labeling.</p> <p>5 Q. When you were involved with -- I'm going</p> <p>6 to talk about the recovery in the G2 filter right now.</p> <p>7 You knew that there were issues with</p> <p>8 both of those devices not staying perfectly centered in</p> <p>9 the vena cava, true?</p> <p>10 A. I knew there were reports of complaints</p> <p>11 where there was tilting.</p> <p>12 Q. And that tilting was a condition that</p> <p>13 could put a patient at an increased risk of</p> <p>14 perforations, of migrations, of fracture and of the</p> <p>15 device not working for its intended purpose of stopping</p> <p>16 pulmonary embolisms.</p> <p>17 Did you know that?</p> <p>18 A. The tilting could contribute to that.</p> <p>19 Q. And do you know that you could see 15,</p> <p>20 20 degrees or any type of degree tilting of a filter on</p> <p>21 a plain view x-ray?</p> <p>22 A. The cavagrams can display tilting to a</p> <p>23 certain degree.</p> <p>24 Q. Okay. And the company's knowledge that</p>	<p style="text-align: right;">Page 73</p> <p>1 and becoming embedded in the wall of the vena cava,</p> <p>2 requiring other problems?</p> <p>3 MS. DALY: Objection, lack of</p> <p>4 foundation.</p> <p>5 THE WITNESS: I never saw data that</p> <p>6 indicated that, but it could be.</p> <p>7 BY MR. LOPEZ:</p> <p>8 Q. Yes, you did, I'm going to show it to</p> <p>9 you later.</p> <p>10 A. Okay. I can't recall.</p> <p>11 Q. Okay. And that tilting, in addition to</p> <p>12 those other things I just mentioned, can also result in</p> <p>13 the tip of the filter and the legs of the filter</p> <p>14 becoming so embedded and being in such a position</p> <p>15 within the cava that it cannot be retrieved via a</p> <p>16 percutaneous approach, true?</p> <p>17 A. Tilting would make it very difficult to</p> <p>18 retrieve.</p> <p>19 Q. Right. Don't you think doctors and</p> <p>20 patients should have known that?</p> <p>21 A. What?</p> <p>22 Q. By the way, if this thing starts to</p> <p>23 tilt, maybe you ought to take it out before it becomes</p> <p>24 embedded in the side wall of the vena cava; don't you</p>

19 (Pages 70 to 73)

EXHIBIT E

Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study

Christoph A. Binkert, MD, MBA, Alain T. Drooz, MD, James G. Caridi, MD, Mark J. Sands, MD, Haraldur Bjarnason, MD, Frank C. Lynch, MD, William S. Rilling, MD, Domenic A. Zambuto, MD, S. William Stavropoulos, MD, Anthony C. Venbrux, MD, and John A. Kaufman, MD

PURPOSE: To assess the technical success and safety for retrieval of the G2 filter.

MATERIALS AND METHODS: The authors performed a prospective, multicenter study of 100 patients with temporary indication for caval interruption. Patients were enrolled consecutively between December 2005 and July 2006. There were 67 men and 33 women with a mean age of 52.1 years (range, 19–82 years). Indications for filter placement were trauma ($n = 56$), perioperative risk ($n = 16$), and medical indications ($n = 28$). Forty-two patients had venous thromboembolism at filter placement. Fifty-eight filters were placed prophylactically.

RESULTS: Retrieval was attempted in 61 patients. Fifty-eight of the 61 filters (95%) were successfully retrieved after a mean dwell time of 140 days (range, 5–300 days). In all failed retrievals, the filter tip was against the caval wall. There was no difference in dwell times between successful and unsuccessful retrievals. Although there were no cases of cranial migration, caudal migrations were observed in 12% of cases (10 of 85 patients with a complete data set). Other device-related complications included filter fracture (1/85, 1.2%), filter tilt of more than 15° (15/85, 18%), and leg penetration (16/61, 26%). The recurrent pulmonary embolism (PE) rate was 2%, with no PE in the 30-day period after filter retrieval.

CONCLUSIONS: Retrieval of the Recovery G2 filter was safe and successful in most patients. Caudal migration was observed as an unexpected phenomenon.

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Abbreviations: DVT = deep venous thrombosis, IVC = inferior vena cava, PE = pulmonary embolism, VTE = venous thromboembolism

VENOUS thromboembolism (VTE) is a leading cause of death in hospitalized patients (1–3). Anticoagulation is the standard therapy for VTE, but in certain cases anticoagulation may be contraindicated for short- or long-term VTE therapy.

Inferior vena cava (IVC) filters have been shown to successfully prevent pulmonary embolism (PE) (4). However, although IVC filters decrease the risk of PE in the short term, they are associated with a higher incidence of deep vein thrombosis (DVT) after 2 and

8 years (5,6). The observation of Decousus et al (5) stimulated the idea of optional filters. Optional filters are permanent filters with the “option” to be retrieved if they are no longer clinically needed to avoid possible long-term adverse effects of permanent filters.

The G2 filter (Bard Peripheral Vascular, Tempe, Arizona) is a second-generation optional filter with an updated design compared to the original Recovery filter (Bard Peripheral Vascular). The permanent use of the G2 filter for the prevention of PE was previously reported (7–10). The purpose of this study was to assess the retrievability of the G2 filter.

MATERIALS AND METHODS

Study Design

This prospective single-arm multicenter Investigational Device Exemption clinical study, sponsored by Bard Peripheral, was conducted in accor-

From the Department of Radiology, Brigham and Women's Hospital/Harvard Medical School, Boston, Massachusetts (C.A.B.); Department of Radiology, Inova Fairfax Hospital, Falls Church, Virginia (A.T.D.); Department of Radiology, University of Florida, Gainesville, Florida (J.G.C.); Department of Radiology, Cleveland Clinic, Cleveland, Ohio (M.J.S.); Department of Radiology, Mayo Clinic, Rochester, Minnesota (H.B.); Department of Radiology, Penn State Milton S. Hershey, Hershey, Pennsylvania (F.C.L.); Department of Radiology, Froedtert Memorial Lutheran Hospital, Milwaukee, Wisconsin (W.S.R.); Department of Radiology, Hartford Hospital, Hartford, Connecticut (D.A.Z.); Department of Radiology, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania (S.W.S.); Department of Radiology, George Washington University Medical Center, Washington, DC (A.C.V.); and Department of Radiology, Dotter Interventional

Institute, Portland, Oregon (J.A.K.). Received February 12, 2009; final revision received August 9, 2009; accepted August 13, 2009. **Address correspondence** to C.A.B., Institute of Radiology, Kantonsspital Winterthur, Brauerstrasse 15, 8401 Winterthur, Switzerland; E-mail: christoph.binkert@ksw.ch

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dance with the SIR reporting standards (11) at 11 sites within the United States: Brigham & Women's Hospital, Boston, Massachusetts; Inova Fairfax Hospital, Falls Church, Virginia; University of Florida, Gainesville, Florida; Dotter Interventional Institute-OHSU, Portland, Oregon; Cleveland Clinic, Cleveland, Ohio; Mayo Clinic, Rochester, Minnesota; Penn State, Hershey, Pennsylvania; Hartford Hospital, Hartford, Connecticut; Froedtert Memorial Lutheran Hospital, Milwaukee, Wisconsin; Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; and George Washington University Medical Center, Washington, DC.

Patients were consecutively enrolled from December 2005 through July 2006. All patients were informed of the risks and benefits of participating in the study and gave written informed consent to participate before enrollment. The protocol was approved by the institutional review board at each study site, and all study procedures were conducted in accordance with Good Clinical Practices.

Study procedures included ultrasonographic (US) screening for a patent jugular vein to be used for future filter retrieval, placement of the study filter, and conventional radiographic examination of the abdomen in full expiration (anteroposterior, lateral, and bilateral anterior-oblique projections) within 48 hours after filter placement. If the filter was not retrieved, a phone assessment was conducted at 3 months and a clinic visit at 6 months, including repeat conventional radiography.

The indication for filter retrieval was discussed with the referring medical team. Filter retrieval was performed if there was no longer an increased risk for PE and/or no longer a contraindication to anticoagulation. Vascular US of the deep vein system was performed beforehand in patients with prophylactic filter placement. If no DVT was found, no further anticoagulation was undertaken. If a DVT was found in these patients and in all patients with known DVT or PE, a 6-month course of anticoagulation was carried out. A cavogram with iodinated contrast medium was obtained before and after filter retrieval in all patients. In addition, a follow-up clinic visit was required 1 month after retrieval.

Patient Population

One hundred patients (67 men, 33 women) were included in the study. The mean patient age was 52.1 years (range, 19–82 years). Patients considered for inclusion in the study were temporarily at increased risk for PE with a need for caval interruption because of a contraindication of anticoagulation. The indication for filter placement is summarized in the **Table**. Additional study requirements included an estimated life expectancy of more than 6 months, a normal right-sided IVC with a diameter less than 28 mm, and a serum creatinine level of less than 2.0 mg/dL (176.8 μ mol/L) for safe application of iodinated contrast medium.

Forty-two patients presented with VTE at filter placement: 18 had DVT only, 10 had PE only, and 14 had both DVT and PE. Of the 58 patients without VTE, 10 had a history (>3 months) of VTE.

Device

The devices used in this study were the G2 filter (**Figure**) and the Recovery Cone Removal System (Bard Peripheral Vascular). The filter consists of 12 shape-memory nitinol wires emanating from a central nitinol sleeve. The wires form two levels of filtration, with the legs (leg span, 40 mm; overall height, 39 mm) providing the lower level of filtration and the arms (arm length, 18.5 mm; span, 33 mm) providing the upper level of filtration. The nitinol filter was designed for use in IVCs with diameters less than or equal to 28 mm. The insertion and retrieval techniques were previously described by Oliva et al (12).

Outcome

The primary objective of the study was to assess the technical and clinical success of the G2 filter retrieval, including adverse events within 30 days after retrieval. In addition, we evaluated the overall clinical experience, as assessed by filter migration and filter fracture and relevant placement procedural parameters and outcomes.

Filter migration was defined as a change in filter position compared to its deployed position (either cranial or caudal) of more than 2 cm as documented with plain radiography or venography.

Indications for Filter Placement

Indication for Filter Placement	No. of Patients (n = 100)
Trauma*	56 (56%)
Surgery (within 1 mo)†	16 (16%)
Nonsurgical treatment‡	28 (28%)

* The trauma category includes spine, abdominal, long bone, pelvic, thoracic, and head trauma.

† The surgical category includes surgical patients with a history of or active VTE at the time of filter placement, including those with a primary diagnosis that was bariatric, gastrointestinal, orthopedic (joint replacement, spine), neurosurgical (intracranial, spine), or related to a gynecologic procedure.

‡ The nonsurgical treatment category includes patients with a medical condition preventing safe anticoagulation, including those with a primary diagnosis that was related to cancer (with or without metastases), a gynecologic disorder, hypercoagulopathy (without malignancy), morbid obesity, or stroke (within 6 months).

Filter fracture was defined as any loss of structural integrity (ie, breakage or separation) of the filter documented at imaging. Filter penetration/protrusion was defined as penetration of a filter leg or arm of more than 3 mm outside the IVC measured at venography according to the American College of Radiology Practice Guidelines (13). During the clinical visit 6 months after filter placement or 1 month after filter retrieval, a history and physical examination was performed, focusing on symptoms of PE (shortness of breath) and DVT (leg swelling, leg pain).

RESULTS

Filter Placement

All 100 G2 filters were deployed successfully. For access, the right common femoral vein was used 90 times, and the left common femoral vein was accessed 10 times.

The mean fluoroscopy time was 3.2 minutes (range, 0.4–33.6 minutes). The mean IVC diameter (\pm standard deviation) was 20.5 mm \pm 3.4 (range, 12–28 mm). Two filters were noted to

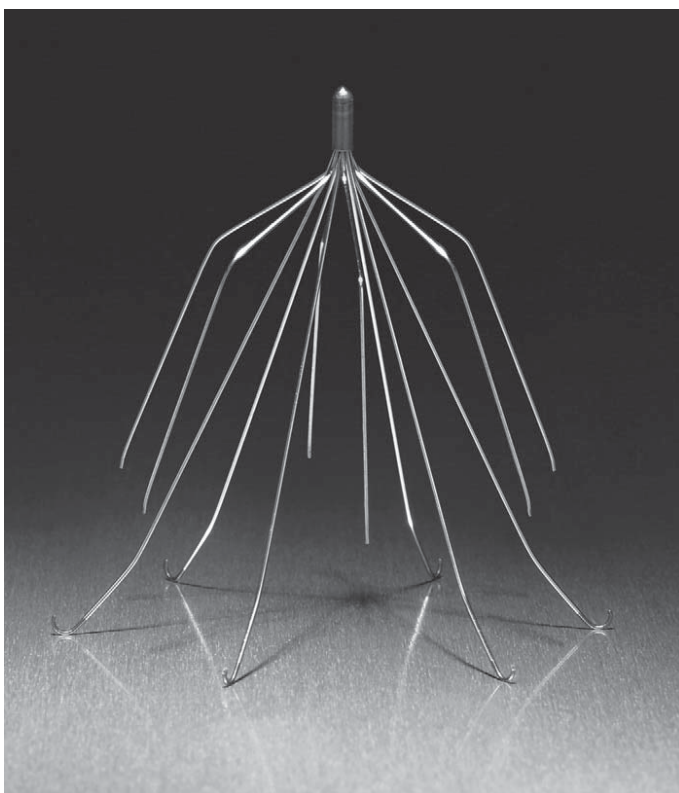


Figure. G2 filter. Compared with the original Recovery filter, the arms are longer and the legs wider. The welding at the tip was also changed.

have had a tilt of more than 15° immediately following placement. Both filters were placed from the right common femoral vein, and no attempt was made to straighten the filters. All imaging studies were assessed by the site investigators.

Postplacement Procedure Follow-up

All patients enrolled in the study were to be followed up to 6 months after filter placement or to 1 month after filter retrieval, whichever came first. A phone call was placed 3 months after filter placement to assess filter retrieval status, current medications, and adverse events. Office visits were scheduled at 6 months after placement if the filter had not been retrieved. A physical examination, current medication assessment, adverse event assessment, and follow-up imaging were completed (supine anteroposterior abdominal radiography in anteroposterior and lateral projections at full expiration and posteroanterior digital spot radiography centered on the filter). If the physician determined that the filter continued to be clinically indi-

cated, the device could be left in place permanently. At study completion, 83 of the 100 patients enrolled had a complete data set for evaluation (see Final Follow-up).

Filter Retrieval

Retrieval was attempted in 61 patients. The right internal jugular vein was used for access in all cases. In 58 of the 61 patients, retrieval was successful. All study retrieval procedures were performed by using standard Recovery cone technique. In three cases, retrieval failed because the filter tip could not be engaged with the cone as the filter tip was embedded in the IVC wall.

The mean fluoroscopy time for the attempted filter retrievals, as recorded in 59 of the 61 patients, was 7.4 minutes \pm 10.5 (range, 1.4–59.8 minutes). The mean fluoroscopy time for successful retrieval procedures (56/58 recorded values) was 6.3 minutes \pm 8.5 (range, 1.4–59.63 minutes). The mean fluoroscopy time of unsuccessful retrieval attempts was 27.8 minutes

(range, 2.4–48.3 minutes). The significantly longer fluoroscopy times for the unsuccessful retrievals are indicative of more difficulties during retrieval attempt ($P = .03$).

The mean filter dwell time in the 61 patients in whom retrieval was attempted was 138 days (range, 5–300 days). The mean dwell time in patients with successfully retrieved filters was 140 days (range, 5–300 days). The mean dwell time in patients with failed retrievals was 107 days (range, 92–134 days). There was no statistically significant difference between the dwell times of successful versus unsuccessful retrievals ($P = .11$).

Venography was normal in 52 of the 61 attempted retrievals (in one case, venograms were lost). In eight cases, venograms were reported as abnormal. Four venograms showed a small thrombus in the filter. In three cases, a stenosis was noted at the filter level of the IVC before retrieval and in two cases there was a stenosis after retrieval secondary to difficulties during filter retrieval. One stenosis was measured at more than 50%; however, there were no related clinical sequelae noted at the 1-month follow-up visit. In one case, both a stenosis of the IVC and a thrombus in the filter was documented.

Final Follow-up

Overall, 83 of 100 patients had a complete data set either with successful retrieval or observation for 6 months. Four patients completed all clinical evaluations but were lacking final imaging. Fifty-eight of the 61 attempted filter retrievals were successful. As previously discussed, three filter retrieval attempts were unsuccessful. Fifty-six of the 58 patients completed 1-month follow-up after retrieval; two patients were lost to follow-up. A total of 42 filters were not retrieved. No retrieval attempt was undertaken in 39 patients. Thirty-one of the 42 patients in whom filters were not retrieved completed the 6-month follow-up. However, as mentioned above, the final imaging data set was not available in four patients. Of the 11 patients who did not complete follow-up, six died, three withdrew consent, and two were lost to follow-up as previously discussed. Six deaths were reported between 22 and 100 days after filter placement (mean, 60.6 days). All were due to

pre-existing conditions (colon cancer, cardiac arrest, myocardial infarction, chronic obstructive pulmonary disease, pneumonia, and chondrosarcoma) and were not related to the study device, placement procedure, or retrieval procedure.

During the study, two symptomatic PE were recorded. Both PE occurred with the filter in place. No PE was noted during the 1-month observation period after the filter was removed. No new symptomatic DVT was noted during the study period.

Procedure-related Complications

One hundred filters were successfully deployed in 100 patients. There were four procedure-related complications during the study: three complications occurred during placement and one complication occurred during retrieval. One patient experienced an allergic skin reaction following access site preparation during both implantation and retrieval. One patient had acute renal failure secondary to multiple, same-day contrast studies and one had a hematoma related to device placement; however, all complications were resolved with no clinical sequelae.

Device-related Complications

Migration.—Ten filter migrations of more than 2 cm occurred in the 85 patients (12%) who were assessed for this category at a mean follow-up of 155 days (range, 5–323 days). The mean migration distance observed for the 10 migrated filters was 2.7 cm (range, 2.0–4.1 cm). The 85 filter images analyzed for this endpoint include 58 filters imaged at retrieval and 27 nonretrieved filters imaged at 6 months. All migrations occurred toward the feet (ie, caudal migration). Five of these migrated filters were retrieved successfully and two remained in place after an unsuccessful retrieval attempt. In three cases, no retrieval attempt was performed.

Filter fracture.—One filter fracture occurred in the 85 assessed devices (1.2%). Preretrieval venography performed on day 92 revealed a mild filter tilt with a fractured strut external to the IVC. One arm and one leg were observed outside the IVC. A retrieval attempt was unsuccessful secondary to the apex being embedded in the IVC wall. Nevertheless, this patient re-

mained asymptomatic and without symptoms of PE during final follow-up through day 209.

Filter tilt.—Overall, 15 of the 85 filters (18%) with assessable images showed a tilt of more than 15°. Two previously mentioned filters tilted during placement; the remaining 13 developed tilt during follow-up. Of the 15 tilted filters, 10 were removed successfully and three could not be removed. In two cases, no retrieval attempt was performed. No PE or other adverse event occurred in this group.

Filter penetration.—Assessment of filter penetration was only possible in the 61 patients who underwent venography before filter retrieval. Sixteen of the 61 patients (26%) showed a filter leg or arm penetrated more than 3 mm outside the IVC. Of these 16 patients, 14 had undergone a successful retrieval. Fifteen of 16 patients with penetration were asymptomatic, and one patient reported back pain that was relieved following filter retrieval.

Complication relationship.—The study data show a significant relationship between tilt or more than 15° and migration ($P < .001$); however, there is no statistical evidence that either migration or tilt is related to penetration.

DISCUSSION

In the present study, a relatively high percentage of retrieval attempts were undertaken (61/100). This is similar to that performed in other trials—including the studies by Ray et al (14) (47.7%), Keller et al (15) (49%, 70%), and Wicky et al (16) (67%)—and substantially higher than the retrieval rate in a clinical setup reported by Grande et al (17) (14%). This observation underlines again the importance of an organized follow-up in patients with optional filters.

The retrieval success of the G2 filter in our multicenter study was good, with a technical success rate of 95% (58/61). In a single-center study, Oliva et al (12) had an even higher retrieval rate (100%) for the G2 filter. The retrieval rates for the G2 are similar to those reported for other filter types: The rates for the Günther Tulip filter, the original Recovery filter, the ALN filter (ALN Implants, Chirurgicaux, Ghisonaccia, France), and the OptEase filter (Cordis, Bridgewater, New Jersey) varied from 76% to 98%; 82% to 100%,

50% to 100%, and 91% to 100%, respectively (14,15,17–20). The fluoroscopy times for filter retrieval (mean, 7.4 minutes; range, 1.4–59.8 minutes) were similar to those of other reports with the Günther Tulip filter (Wicky et al [16] reported a mean fluoroscopy time of 6.61 minutes and de Gregorio et al [21] reported a mean fluoroscopy time of 4.4 minutes) and the original Recovery filter (Binkert et al [9] reported a mean fluoroscopy time of 5.8 minutes).

The retrieval rates may have been even higher had alternative retrieval techniques, such as the loop-snare-technique, been applied (22). However, during the present study only the standard retrieval with the Recovery cone was allowed. Retrieval failures were all due to tilted filters with the tips embedded in the IVC wall and were unrelated to dwell time. The mean dwell time in our study was 140 days, which is higher than that reported in most published studies of other filter types—with reported dwell times between 8 and 28 days (15,16,23). The results from the present study suggest that the G2 may likely be retrievable even after 6 months, similar to the reported results with the original Recovery filter (9).

Filter migration is likely the most concerning filter-related complication. Cranial migration was not seen with the G2 filter in our study. Two case reports described migration of a G2 into the right ventricle (24,25). In both case reports the G2 did not open properly and legs entangled within each other, allowing the filter to migrate cranially. It seems that it is important to check for appropriate leg opening of the G2 after placement. Caudal migration, however, was observed in 10 cases in our study (12%). This is a rare phenomenon with a yet unclear mechanism. There is one letter reporting a caudal migration of a G2 filter during carbon dioxide venography (26). The authors hypothesized that caudal filter displacement was due to rapid IVC diameter expansion caudal to the filter caused by carbon dioxide injection. No carbon dioxide was used in the present study, but it is possible that other abrupt changes of the IVC diameter led to caudal migration. The mechanism of caudal migration remains unclear and warrants further investigation. However, the caudal migration of the G2 did not cause any clinical problems in our study.

The frequency of filter fracture and penetration has been reduced compared to original Recovery filter. In our study only one filter fracture (1.2%) was observed. Another study with the G2 reported no fracture (0/51) (12). These rates compare favorably with the reported fracture rate of 7.5% for the original Recovery filter (19). The penetration rate for a filter leg outside the IVC was also reduced—from the reported 62% for the original Recovery filter (19) to 26.2% in our study and to 18% of another study looking at the G2 (12).

The Recovery G2 filter provided a protection against PE in our study. We encountered two PE (2%), which is well within the 5% threshold of the American College of Radiology guidelines and comparable with reported rates of other studies (Grande et al [17%], 2.8%; Ray et al [14], 5%; Keller et al [15], 1.2%; Mismetti et al [18], 2.4%; and Neuerburg et al [27], 2.5%). Importantly, there was no additional PE during the 30-day follow-up after filter retrieval and no new symptomatic DVT caused by the study filter.

The present study has some limitations. The focus was on the technical aspect of the G2 filter. Inclusion criteria to enter the study were quite open, which explains the heterogeneous patient population. Clinical follow-up was performed 6 months after placement and/or 1 month after retrieval. However, during these visits the focus was on detecting clinically significant DVT and/or PE. The venous system was not examined with US for patency or insufficiency. Imaging was performed according to a defined schedule and technique but without a core laboratory for interpretation.

In conclusion, the Recovery G2 filter shows filtration properties that meet the SIR guidelines (28) and which are comparable to other filters. Retrievals were possible after dwell times up to 300 days, similar to the original reported long dwell times of the original Recovery filter. Compared to the original Recovery filter, the new design of the G2 filter showed a decrease in filter fracture and penetration rates. With the adjusted design, cranial migration was successfully avoided in the present study; however, caudal migration of the filter was observed in 12% of cases. The mechanism and the clinical effect of caudal migration warrant further investigation.

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